EXHIBIT A

US008394084B2

(12) **United States Patent**
Palankar et al.

(10) **Patent No.: US 8,394,084 B2**
(45) **Date of Patent: Mar. 12, 2013**

(54) **APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

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(73) Assignee: **Optimedica Corporation**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 896 days.

(21) Appl. No.: **11/328,970**

(22) Filed: **Jan. 9, 2006**

(65) **Prior Publication Data**

US 2006/0195076 A1 Aug. 31, 2006

Related U.S. Application Data

(60) Provisional application No. 60/643,056, filed on Jan. 10, 2005.

(51) **Int. Cl.**
A61B 18/18 (2006.01)

(52) **U.S. Cl.** **606/6**; 606/5

(58) **Field of Classification Search** 606/2–15
See application file for complete search history.

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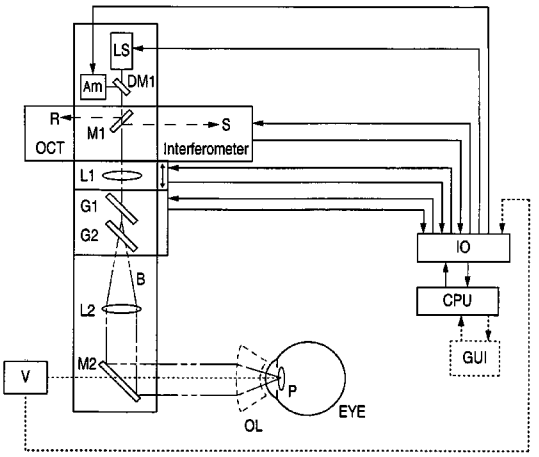
Assistant Examiner — Jeffrey Lipitz
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye tissue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

21 Claims, 10 Drawing Sheets



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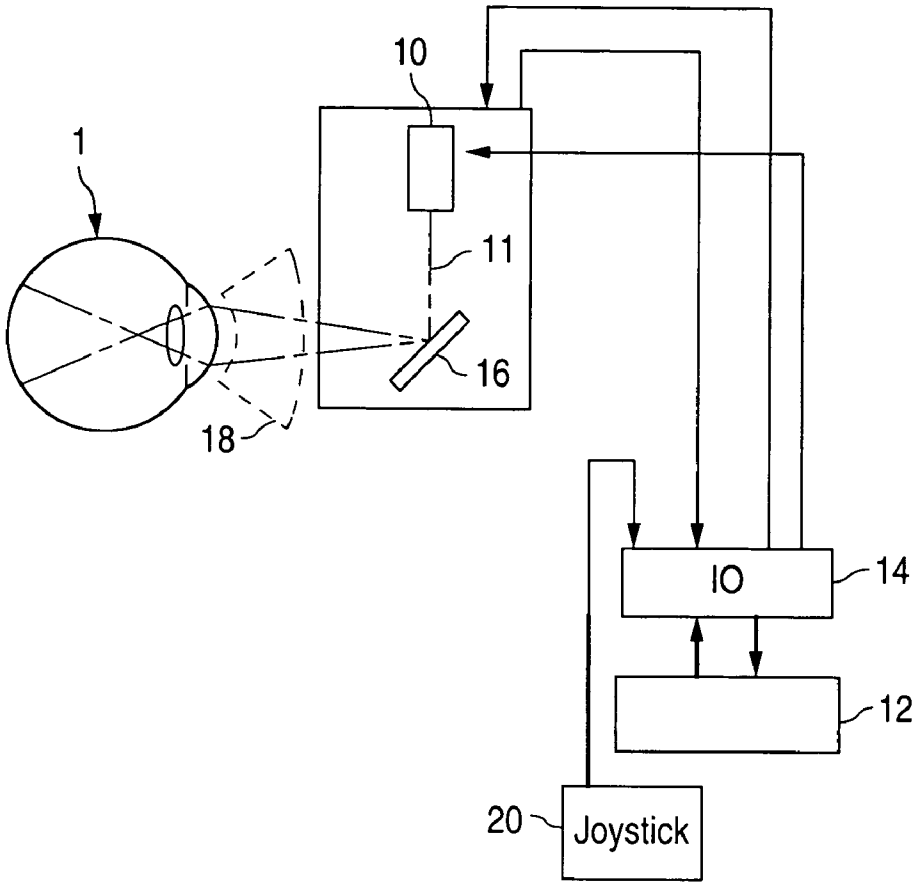

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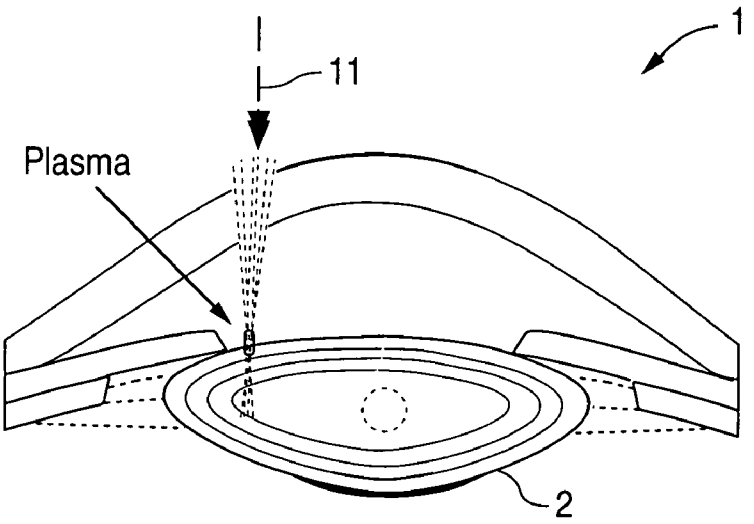

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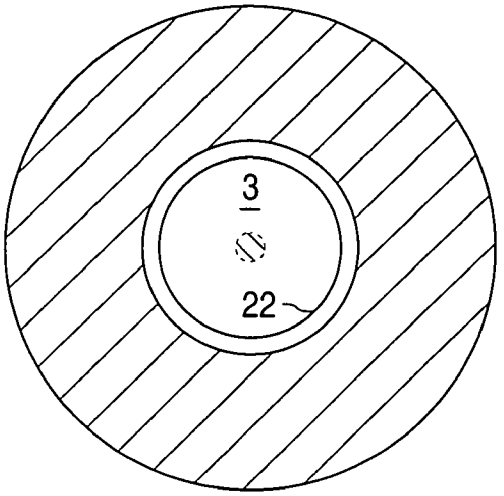

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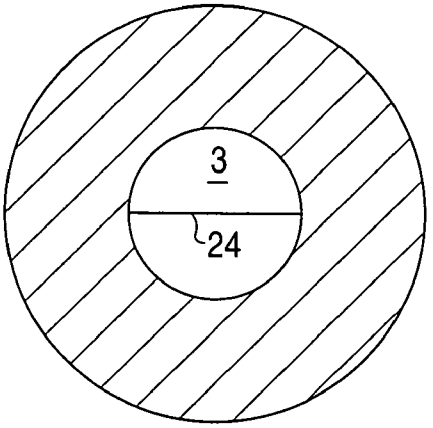

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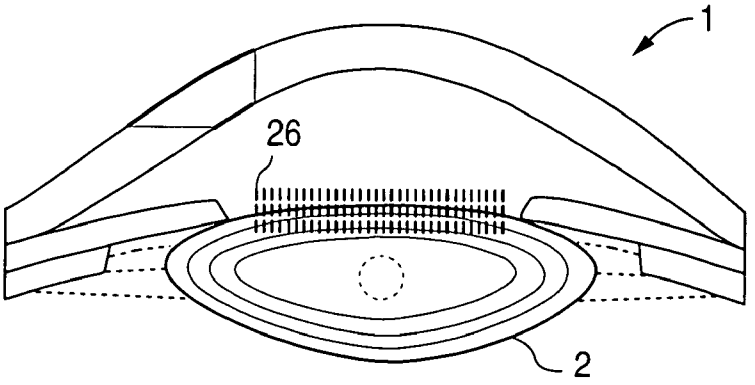


FIG. 5

FIG. 6

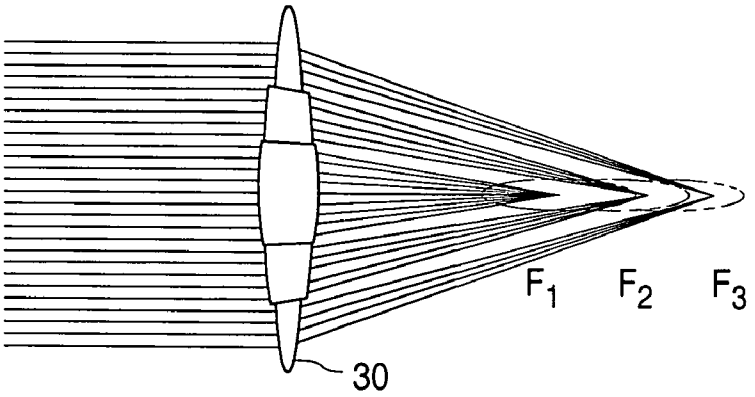
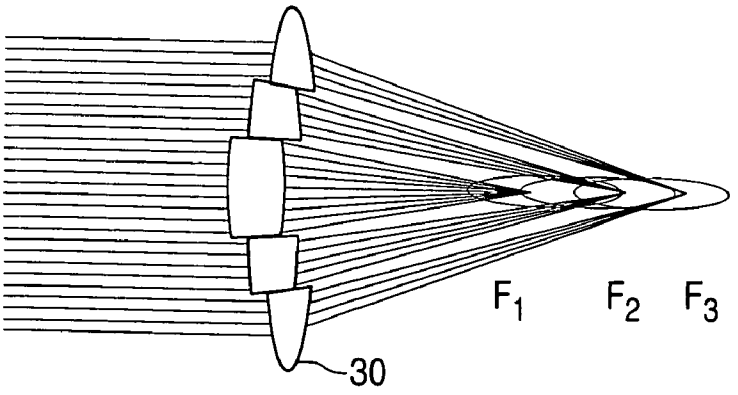


FIG. 7A



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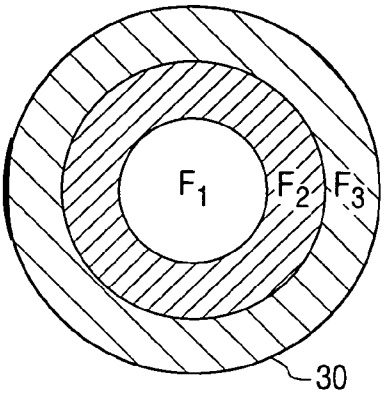
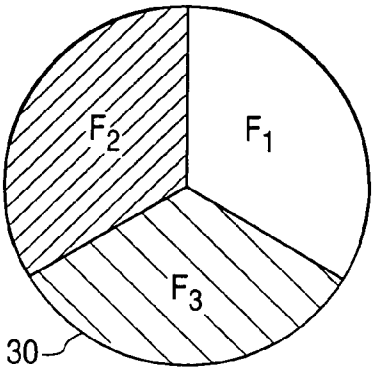


FIG. 7C



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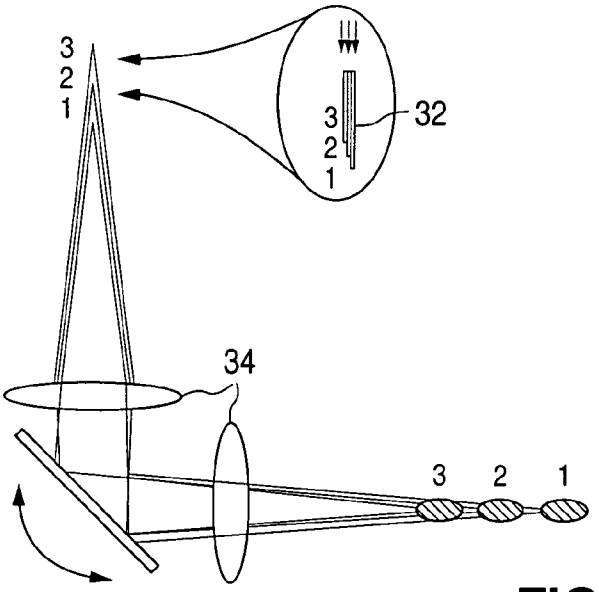

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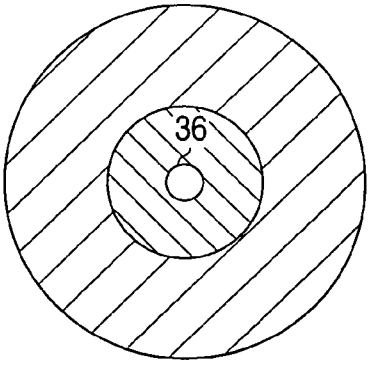


FIG. 9A

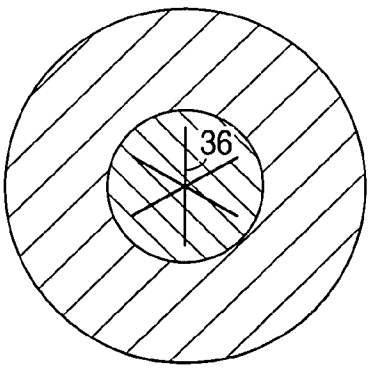


FIG. 9B

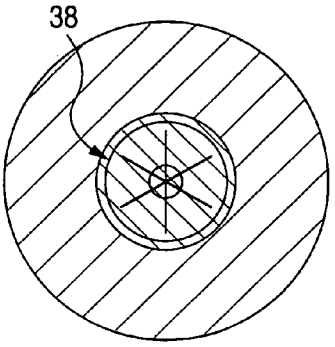
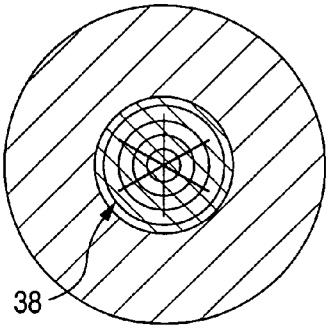


FIG. 10A



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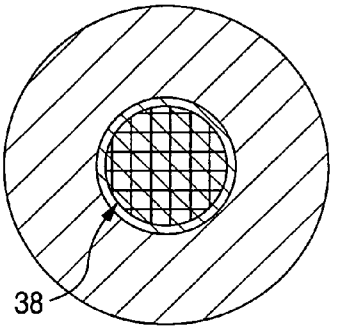

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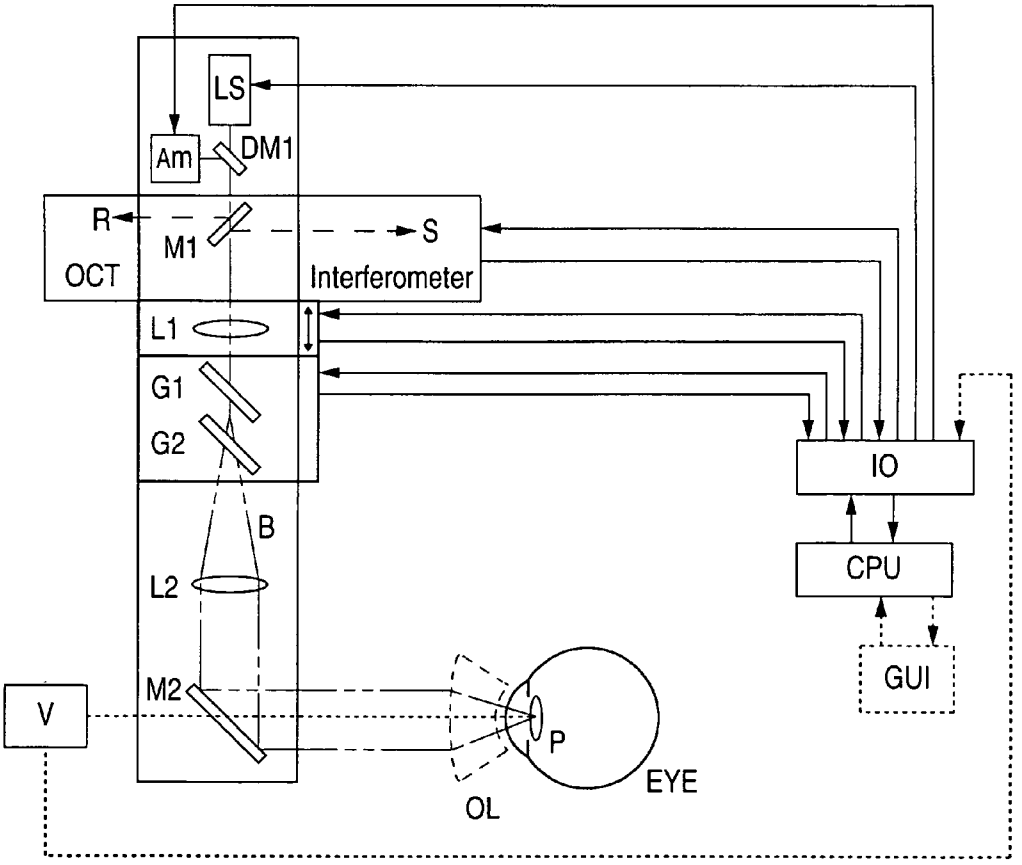

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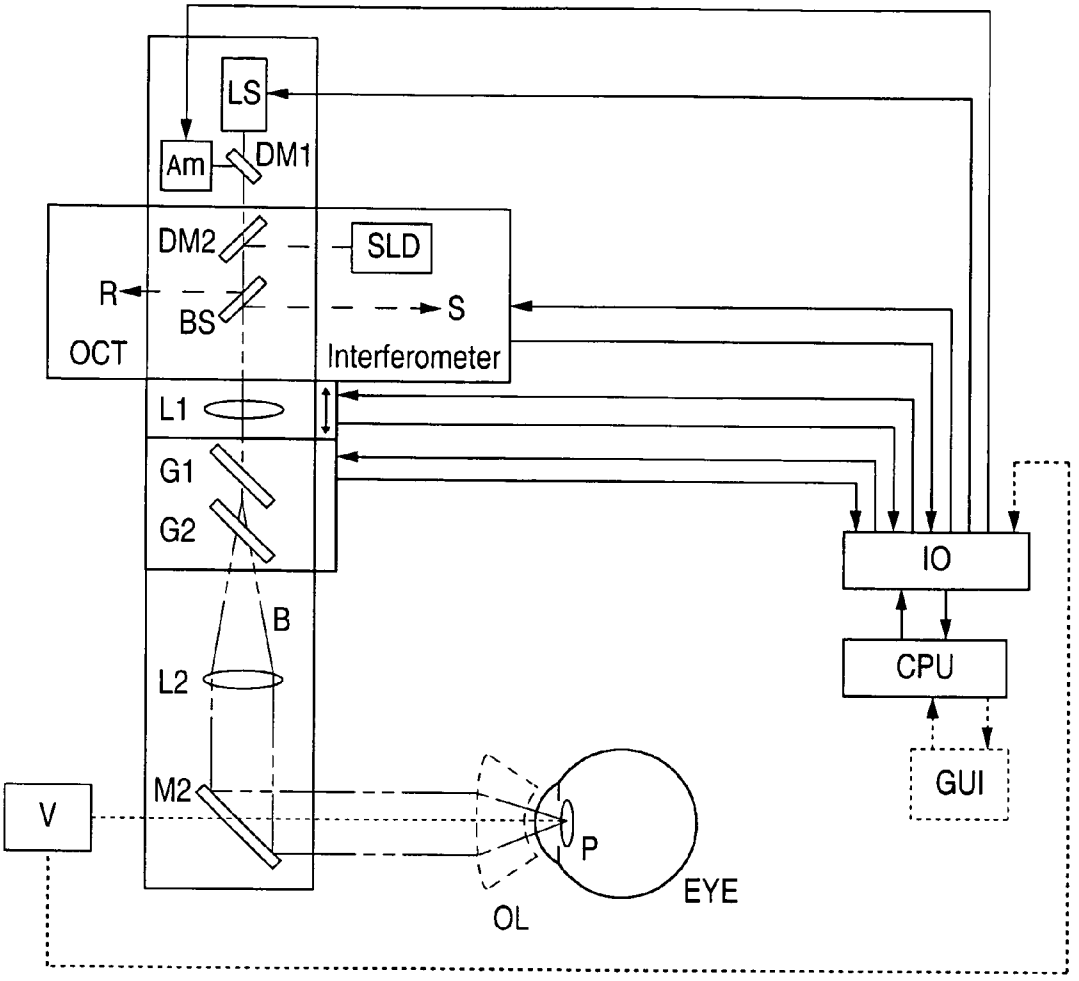

LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

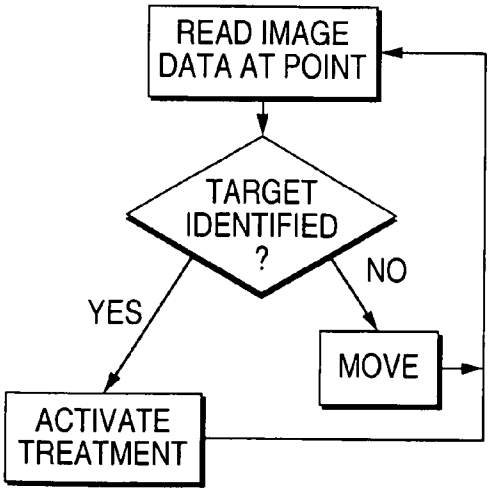

READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

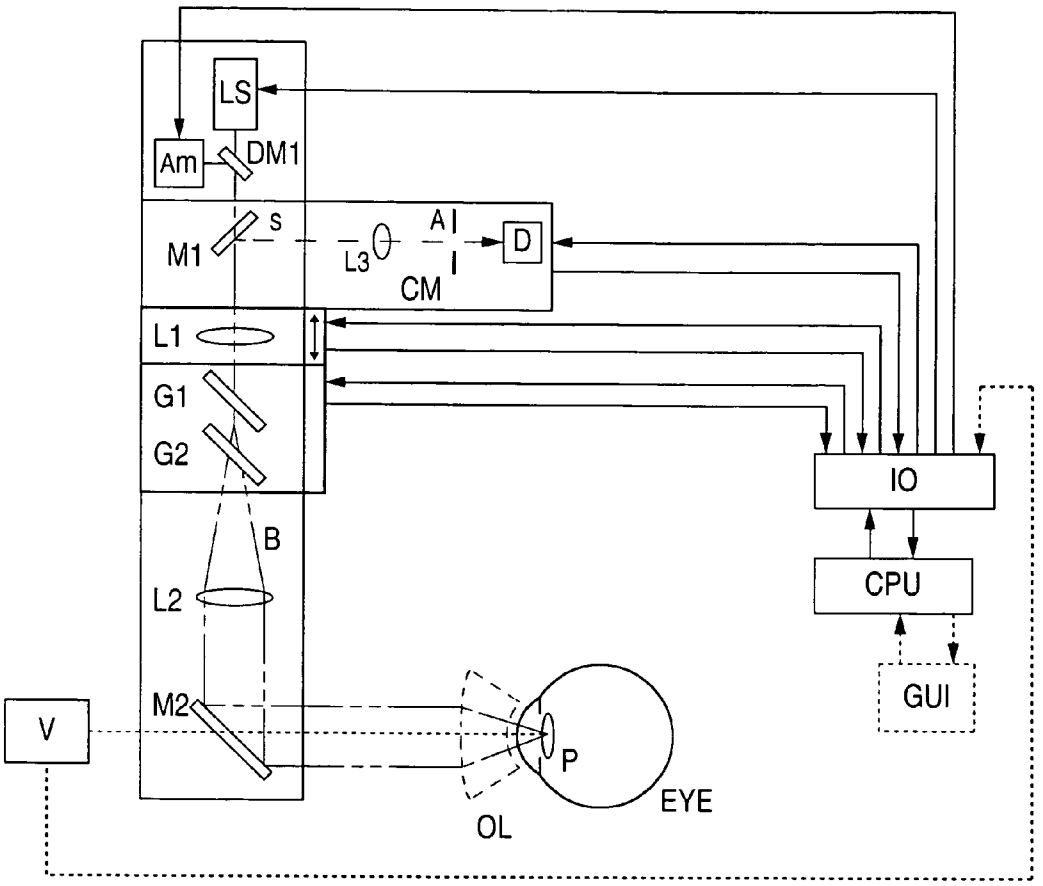


FIG. 13

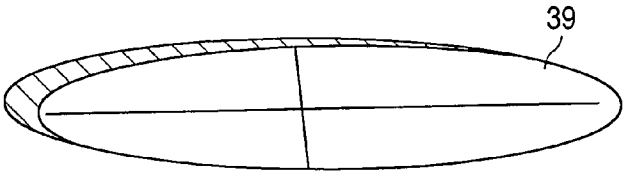


FIG. 16

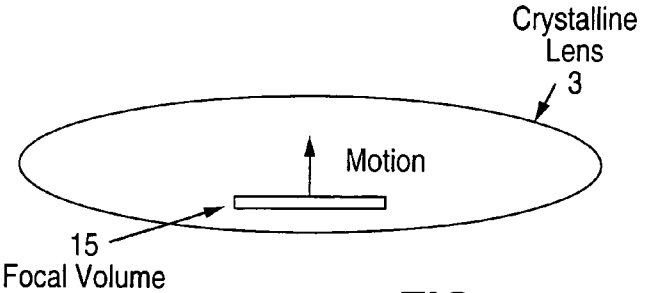


FIG. 19

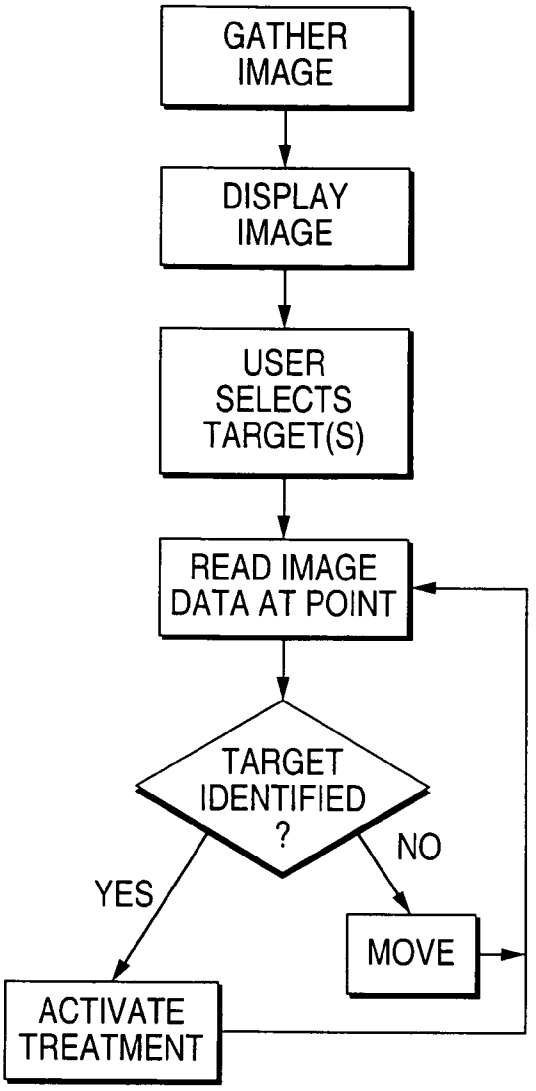

GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

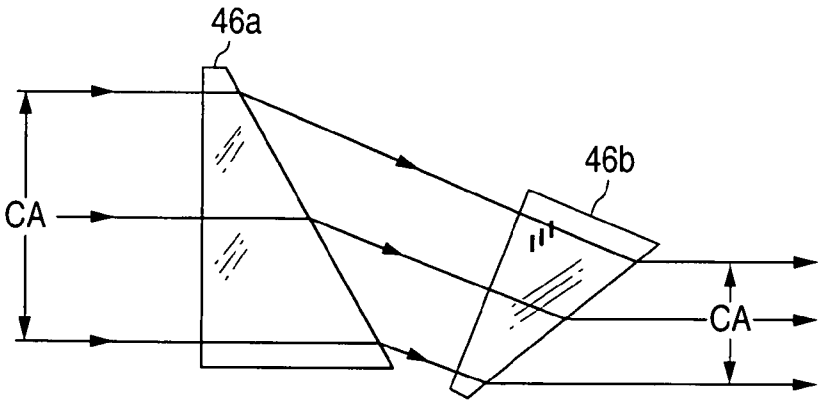

46a
46b
CA
CA

FIG. 18

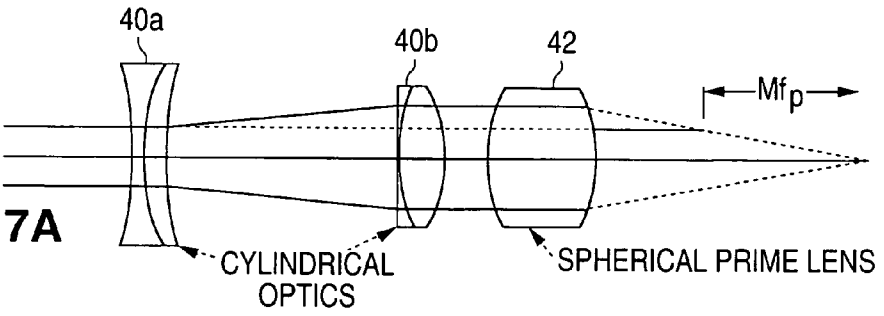


FIG. 17A

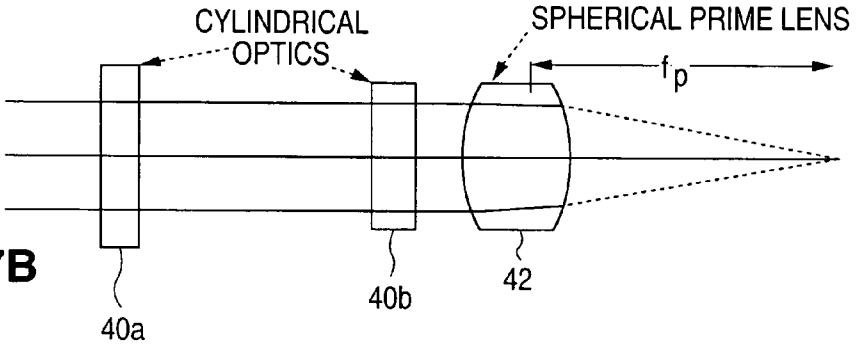


FIG. 17B

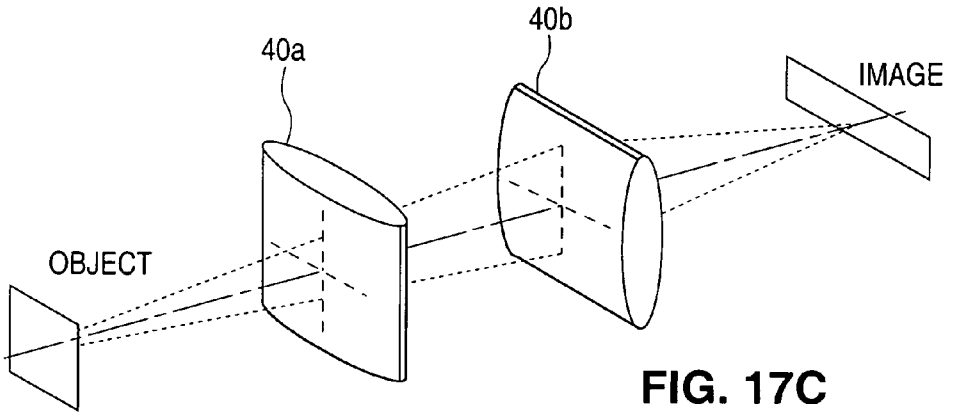


FIG. 17C

FIG. 20

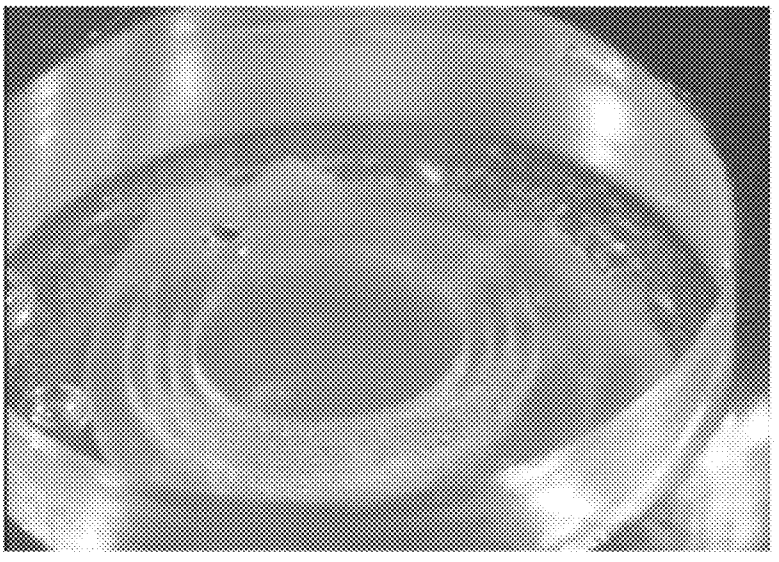


FIG. 21

APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

This application claims the benefit of U.S. Provisional Application No. 60/643,056, filed Jan. 10, 2005.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive* Surgery 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the

appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**,**2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**,**2**,**3**) focused with a set of lenses into multiple points (**1**,**2**,**3**) and thus producing plasma at different depths inside the tissue (**1**,**2**,**3**).

FIG. **9** is a diagram illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ, repetition rate up to 1 MHz, pulse duration <1 ps
2) pulse energy up to 10 μJ, rep. rate up to 100 kHz, pulse duration <1 ps.
3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and λ is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda/(2\cdot NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L\sim\lambda/(4\cdot NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the under-

lying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-co-axial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device IO and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorp-

tion band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm

in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

What is claimed is:

1. A system for cataract surgery on an eye, comprising:

a. a pulsed laser configured to produce a treatment beam which creates dielectric breakdown in a focal zone of the treatment beam within one or more tissue structures of a cataractous crystalline lens;

b. a three-dimensional, optical coherence tomography imaging assembly capable of creating a continuous depth profile of the anterior portion of the cataractous crystalline lens, the profile comprising information regarding the location of a capsule of the cataractous crystalline lens and structures within the crystalline lens, by detecting remitted illumination light from locations distributed throughout a volume of the cataractous crystalline lens, and generating signals based upon the remitted light;

c. an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in the crystalline lens; and

d. one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically:

i. scan tissues of the patient's eye with the imaging assembly so as to generate image data signals to create a continuous depth profile of at least the anterior portion of the lens;

ii. identify one or more boundaries of the one or more tissue structures of the cataractous crystalline lens based at least in part on the image data;

iii. identify one or more treatment regions based upon the boundaries; and

iv. operate the optical scanning system with the pulsed laser to produce a treatment beam directed in a pattern based on the one or more treatment regions so as to create a capsulotomy in the anterior portion of the lens, the treatment beam having a pulse repetition rate between about 1 kHz and about 1,000 kHz, and a pulse energy between about 1 microjoule and about 30 microjoules.

2. The system of claim **1**, wherein the pulsed laser is configured to produce a treatment beam having a wavelength between about 800 nm and about 1,100 nm.

3. The system of claim **1**, wherein the pulsed laser is configured to produce a treatment beam having a pulse repetition rate between about 1 kHz and about 200 kHz.

4. The system of claim **1**, wherein the pulsed laser is configured to produce treatment beam pulses having a pulse duration between about 100 femtoseconds and about 10 picoseconds.

5. The system of claim **1**, wherein the three-dimensional imaging assembly further comprises a second device selected from the group consisting of an interferometer, an optical coherence tomography system, a time domain optical coherence tomography system, a frequency domain optical coherence tomography system, a confocal microscope, and a scanning confocal microscope system.

6. The system of claim **1**, wherein the one or more controllers are further configured to create a pattern of tissue breakdown with the treatment beam to segment one or more of the treatment regions for subsequent removal during cataract surgery.

7. The system of claim **6**, wherein the pattern is configured based at least in part upon a derivation from the signals from the three-dimensional imaging assembly selected from the group consisting of: iris location, pupil diameter, pupil location, posterior lens surface location, anterior lens surface location, posterior lens surface curvature, anterior lens surface curvature, lens outer shape, lens thickness, lens nucleus location, lens nucleus shape, anterior chamber depth, cataract nucleus shape, cataract nucleus location, cataract nucleus thickness, and cataract optical density.

8. The system of claim **6**, wherein the pattern is configured to segment at least a portion of the lens by forming one or more lines using a series of sequential pulses positioned adjacent one another.

9. The system of claim **6**, wherein the pattern is configured to segment a portion of the lens into fragments of sufficiently small size such that they may be removed through a lumen of an ophthalmic aspiration probe.

10. The system of claim **6**, wherein the treatment beam segments the lens tissue into fragments greater than about 1 mm in length.

11. The system of claim **6**, wherein the pattern is configured to segment the crystalline lens along multiple planes.

12. The system of claim **1**, wherein the one or more treatment regions comprise a capsulotomy cutting region transecting the anterior capsule of the lens and a lens segmentation cutting region.

13. The system of claim **1**, wherein the one or more boundaries comprises an anterior lens boundary and a posterior lens boundary.

14. The system of claim **1**, wherein the one or more treatment regions comprise an anterior axial cutting limit and posterior cutting axial limit that is located anterior to the posterior capsule surface.

15. The system of claim **1**, wherein the one or more controllers are programmed to receive input from a user input system and identify the one or more treatment regions based at least in part on the received user input.

16. A system for cataract surgery on an eye, comprising:

a. a pulsed laser configured to produce a treatment beam which creates dielectric breakdown in a focal zone of the treatment beam within one or more tissue structures of a cataractous crystalline lens;

b. a 3-Dimensional optical coherence tomography imaging assembly for imaging the cataractous crystalline lens;

c. an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in the crystalline lens; and

d. one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically:

i. scan tissues of the patient's eye with the imaging assembly so as to detect remitted illumination light from locations distributed throughout a volume of the cataractous crystalline lens and generate image data signals based upon the remitted light to create a continuous depth profile of at least an anterior portion of the lens;

ii. construct an image of at least a portion of the crystalline lens based at least in part upon the signals from the imaging assembly;

iii. identify one or more boundaries of the one or more tissue structures of the cataractous crystalline lens, the one or more boundaries comprising an anterior capsule boundary;

iv. identify one or more treatment regions based upon the boundaries, the one or more treatment regions defining a posterior axial cutting limit that is anterior to the posterior capsule boundary and comprising a capsulotomy cutting region transecting the anterior capsule of the lens; and

v. operate the optical scanning system with the pulsed laser to produce a treatment beam directed in a pattern based on the capsulotomy cutting region so as to create a capsulotomy in the anterior portion of the lens, the treatment beam having a pulse repetition rate between about 1 kHz and about 1,000 kHz, and a pulse energy between about 1 microjoule and about 30 microjoules.

17. The system of claim **16**, wherein the one or more treatment regions comprises a lens segmentation cutting region.

18. The system of claim **17**, wherein the one or more controllers programmed to operate the optical scanning system to direct a treatment beam in a second pattern based on the lens segmentation cutting region so as to fragment the crystalline lens.

19. The system of claim **16**, further comprising a user input system.

20. A system for cataract surgery on an eye, comprising:

a. a pulsed laser configured to produce a treatment beam which creates dielectric breakdown in a focal zone of the treatment beam within one or more tissue structures of a cataractous crystalline lens;

b. a 3-Dimensional optical coherence tomography imaging assembly capable of creating a continuous depth profile of the anterior portion of the cataractous crystalline lens

comprising detecting remitted illumination light from locations distributed throughout a volume of the cataractous crystalline lens and generating signals based upon the remitted light;

c. an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in the crystalline lens; and

d. one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically:

i. scan tissues of the patient's eye with the imaging assembly so as to detect remitted illumination light from locations distributed throughout a volume of the cataractous crystalline lens and generate image data signals based upon the remitted light;

ii. construct an image of at least a portion of the crystalline lens based at least in part upon the signals from the imaging assembly;

iii. identify one or more boundaries of the one or more tissue structures of the cataractous crystalline lens, the one or more boundaries comprising an anterior capsule boundary and a posterior capsule boundary;

iv. identify one or more treatment regions based upon the boundaries, the one or more treatment regions comprising a first cutting region transecting the anterior capsule of the lens and a second region comprising a lower axial cutting limit that is anterior to the posterior capsule; and

v. operate the optical scanning system with the pulsed laser to produce a treatment beam directed in a first pattern based on a first treatment region so as to create a capsulotomy in the anterior portion of the lens, and a second pattern based on a second treatment region so as to fragment the crystalline lens, the treatment beam having a pulse repetition rate between about 1 kHz and about 1,000 kHz, and a pulse energy less than about 30 microjoules.

21. A system for cataract surgery on an eye, comprising:

a. a pulsed laser configured to produce a treatment beam which creates dielectric breakdown in a focal zone of the treatment beam within one or more tissue structures of a cataractous crystalline lens;

b. a three-dimensional imaging assembly capable of creating a continuous depth profile of the anterior portion of the cataractous crystalline lens, the profile comprising information regarding the location of a capsule of the cataractous crystalline lens and structures within the crystalline lens, by detecting remitted illumination light from locations distributed throughout a volume of the cataractous crystalline lens, and generating signals based upon the remitted light;

c. an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in the crystalline lens; and

d. one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically:

i. scan tissues of the patient's eye with the imaging assembly so as to generate image data signals to create a continuous depth profile of at least the anterior portion of the lens;

ii. identify one or more boundaries of the one or more tissue structures of the cataractous crystalline lens based at least in part on the image data;

iii. identify one or more treatment regions based upon the boundaries; and

iv. operate the optical scanning system with the pulsed laser to produce a treatment beam directed in (a) a first pattern based on the one or more treatment regions so as to create a capsulotomy in the anterior portion of the lens; and (b) a second pattern to effect cutting of lens tissue of the target region into a plurality of patterned segments or fragmented pieces for subsequent removal, the treatment beam having a pulse repetition rate between about 1 kHz and about 1,000 kHz, and a pulse energy between about 1 microjoule and about 30 microjoules.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,394,084 B2
APPLICATION NO. : 11/328970
DATED : March 12, 2013
INVENTOR(S) : Daniel V. Palanker et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page, at item (12) Inventors: Please replace "Palankar et al." with "Palanker et al."

Title Page, at item (75) Inventors: Please replace "Daniel V. Palankar" with "Daniel V. Palanker"

Signed and Sealed this
Twenty-third Day of April, 2013

Teresa Stanek Rea
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,394,084 B2
APPLICATION NO. : 11/328970
DATED : March 12, 2013
INVENTOR(S) : Palanker et al.

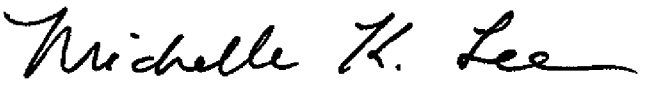
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 985 days.

Signed and Sealed this
Second Day of December, 2014



Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

EXHIBIT B

US008403921B2

(12) **United States Patent**
Palankar et al.

(10) **Patent No.: US 8,403,921 B2**
(45) **Date of Patent: *Mar. 26, 2013**

(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

(75) Inventors: **Daniel V. Palankar**, Sunnyvale, CA (US); **Mark S. Blumenkranz**, Portola Valley, CA (US); **Dan E. Andersen**, Menlo Park, CA (US); **David H. Mordaunt**, Los Gatos, CA (US)

(73) Assignee: **Optimedica Corporation**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/587,833**

(22) Filed: **Aug. 16, 2012**

(65) **Prior Publication Data**

US 2012/0316545 A1 Dec. 13, 2012

Related U.S. Application Data

(63) Continuation of application No. 11/328,970, filed on Jan. 9, 2006.

(60) Provisional application No. 60/643,056, filed on Jan. 10, 2005.

(51) **Int. Cl.**
A61B 18/18 (2006.01)

(52) **U.S. Cl.** **606/6**; 606/2; 606/4

(58) **Field of Classification Search** 606/4, 5, 606/11, 12, 16, 6

See application file for complete search history.

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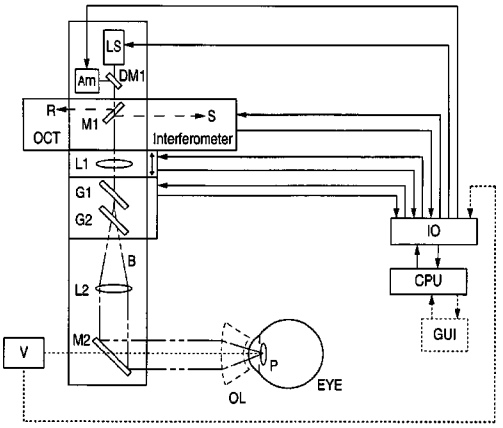
Primary Examiner — Bill Thomson
Assistant Examiner — Jeffrey Lipitz
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye tissue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

23 Claims, 10 Drawing Sheets



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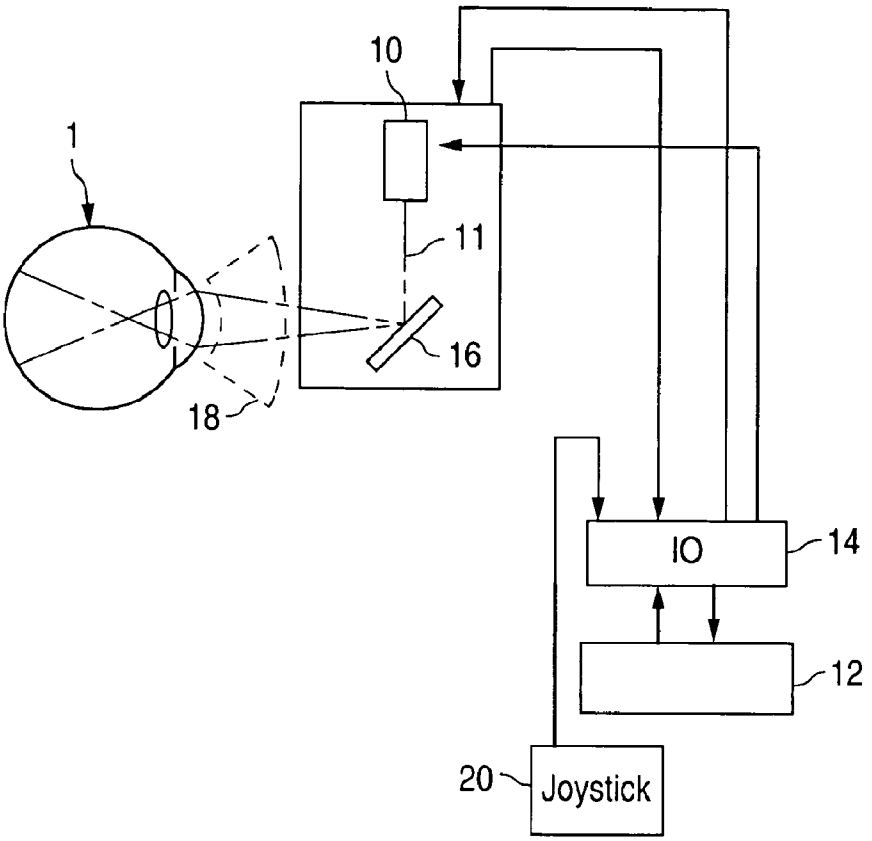

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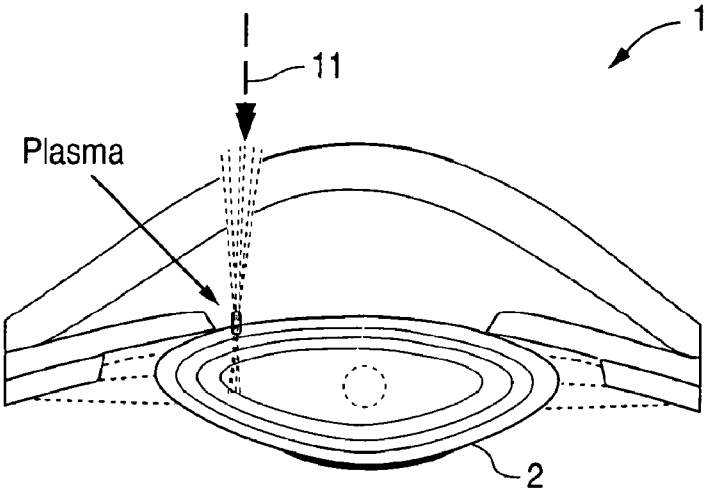

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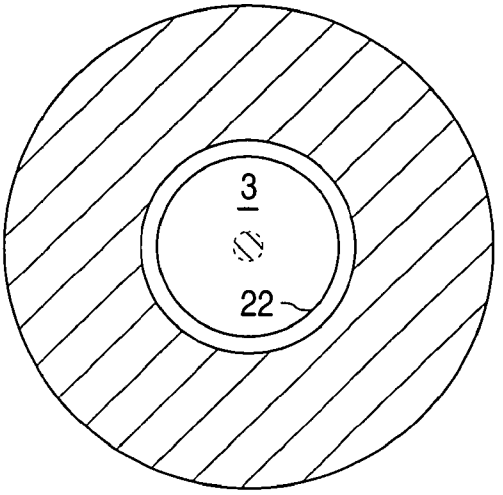

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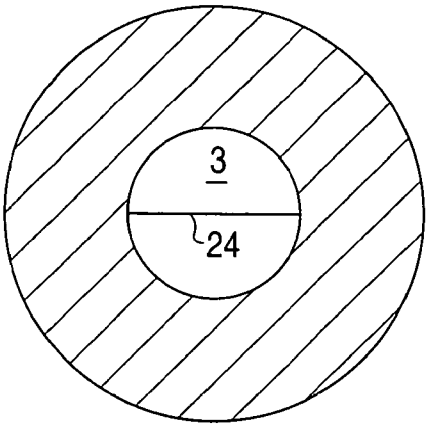

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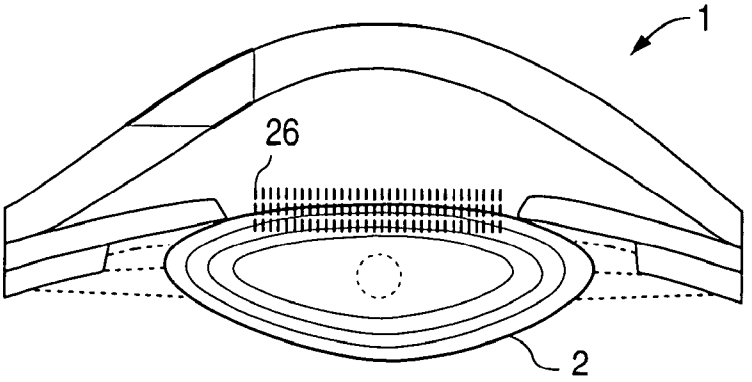

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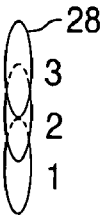

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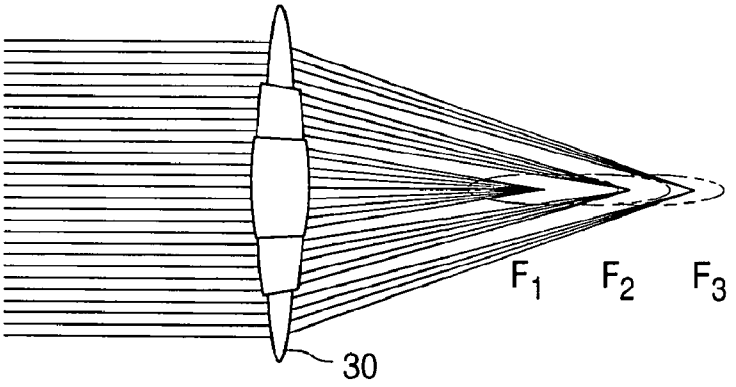
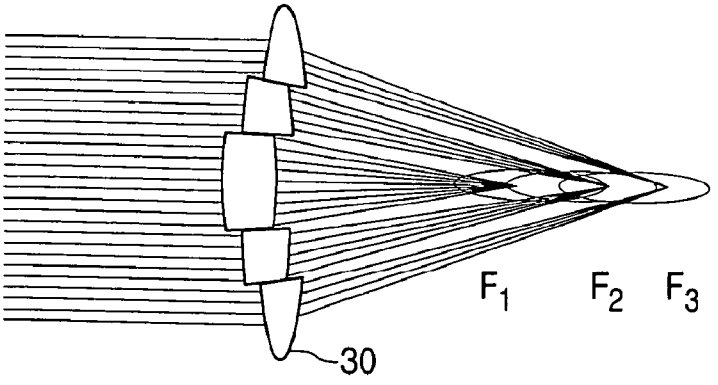


FIG. 7A



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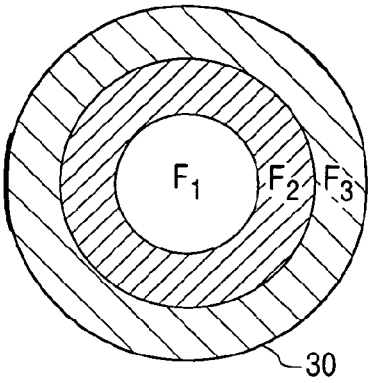

FIG. 7C

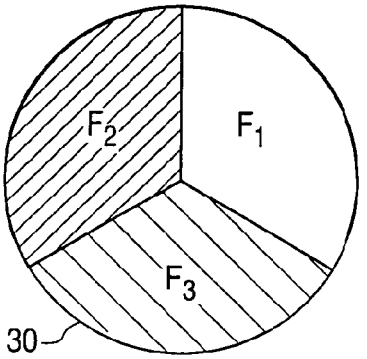

FIG. 7D

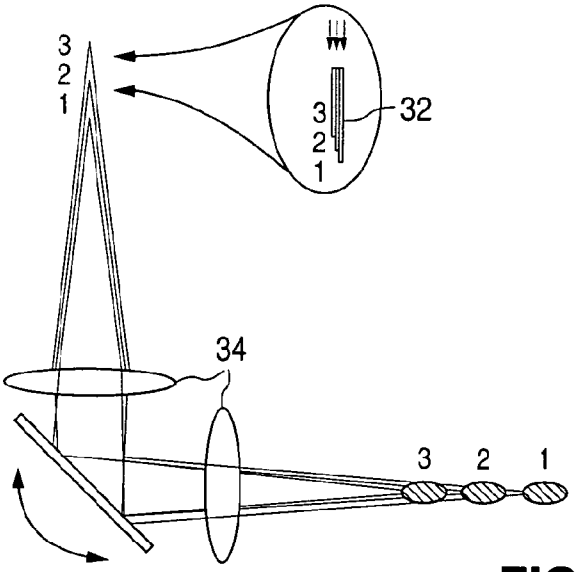

FIG. 8

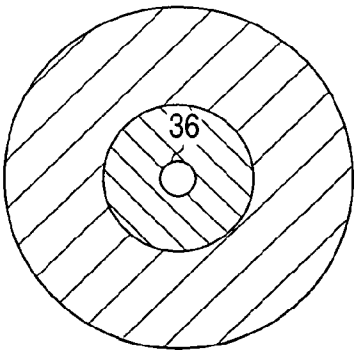

FIG. 9A

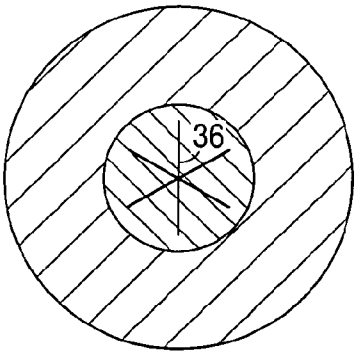

FIG. 9B

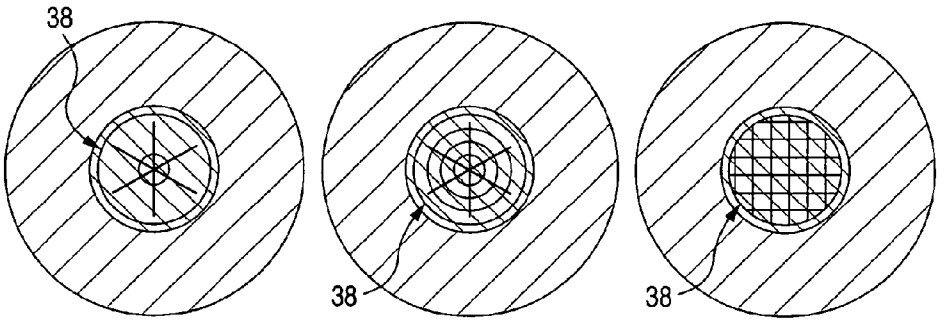

FIG. 10A FIG. 10B FIG. 10C

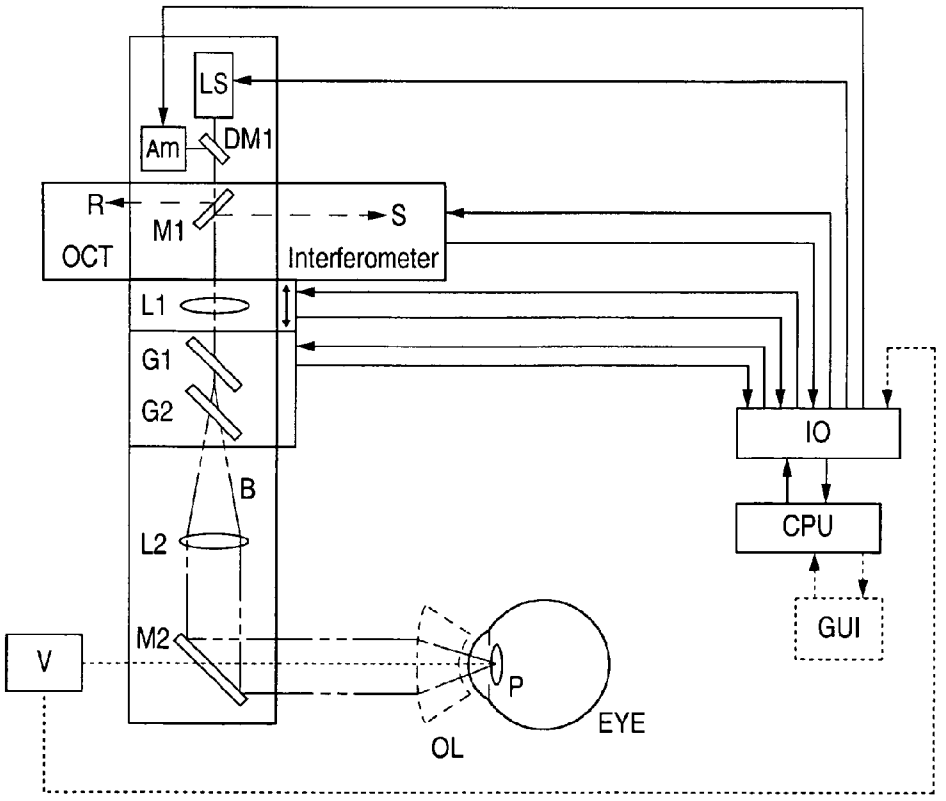

FIG. 11

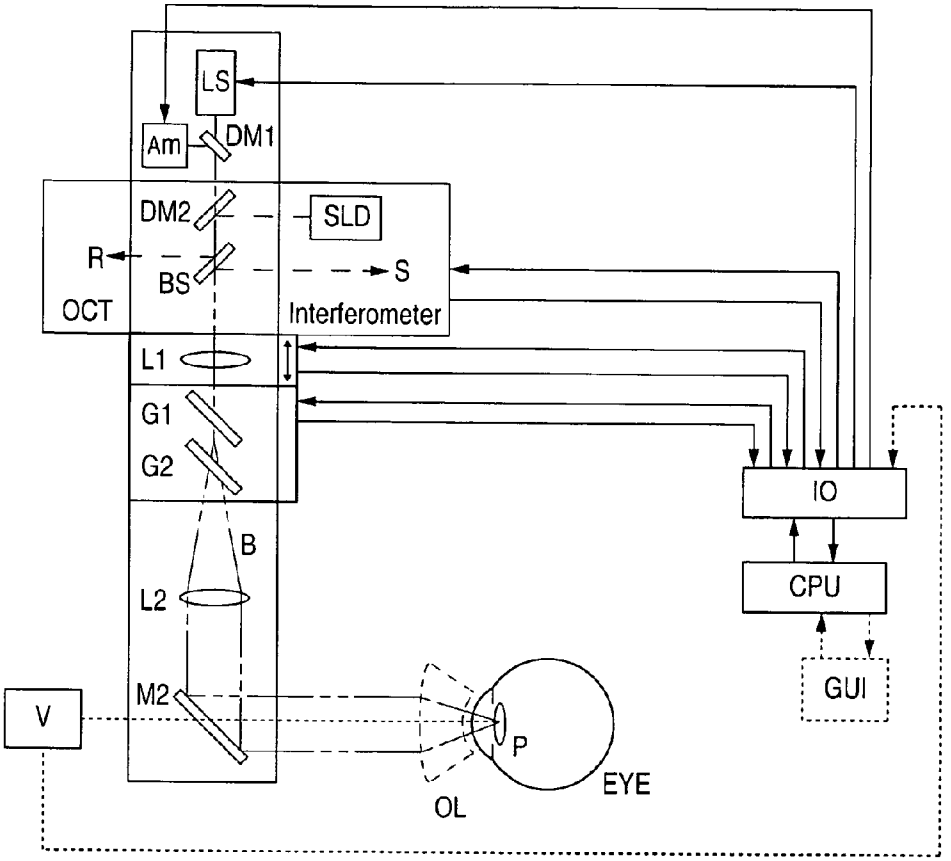
LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

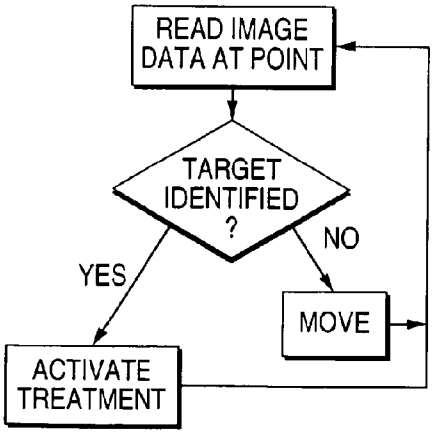
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

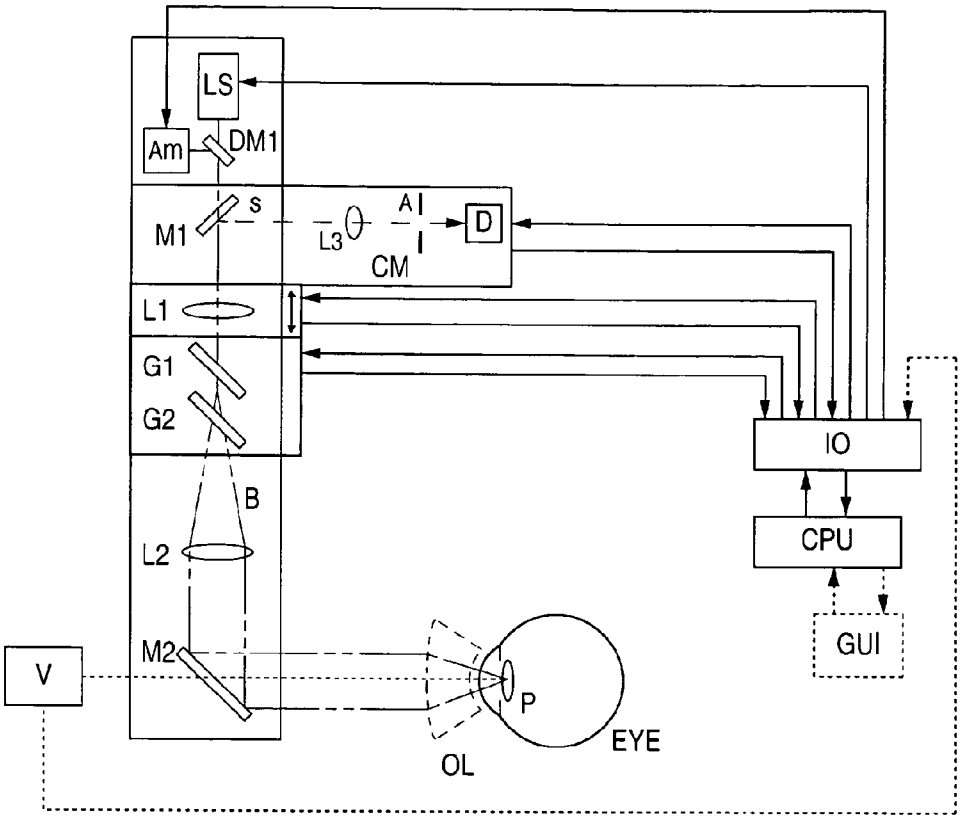

FIG. 13

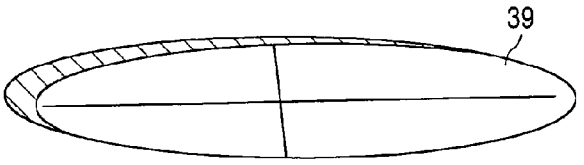

FIG. 16

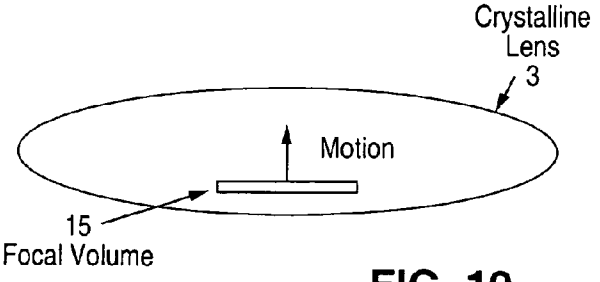

FIG. 19

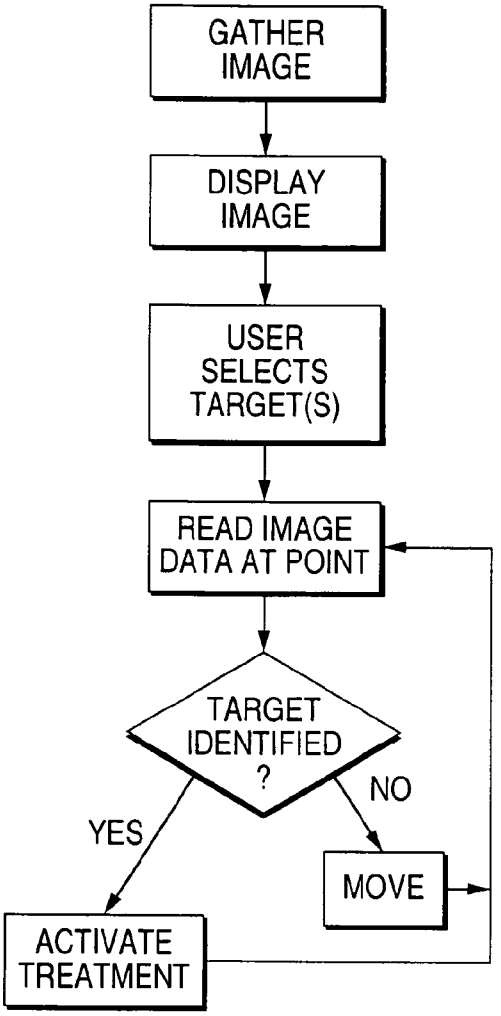
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

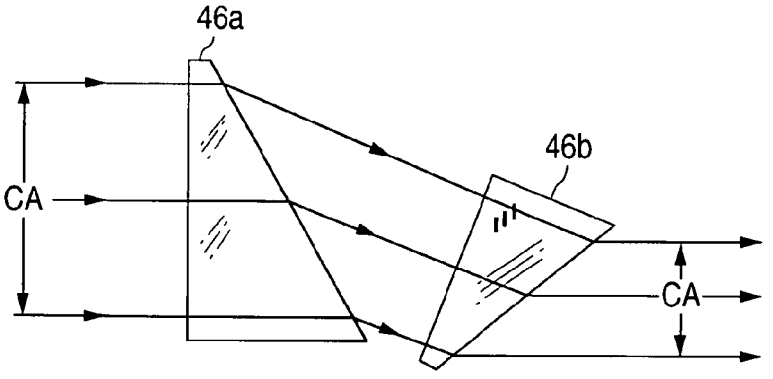
46a
46b
CA
CA

FIG. 18

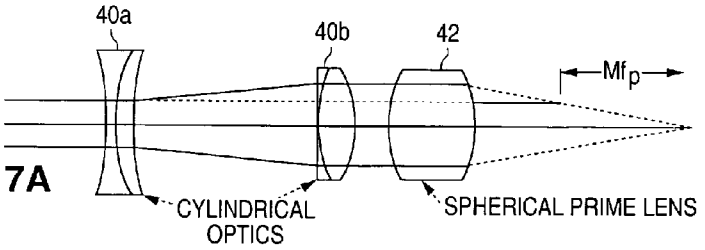

FIG. 17A

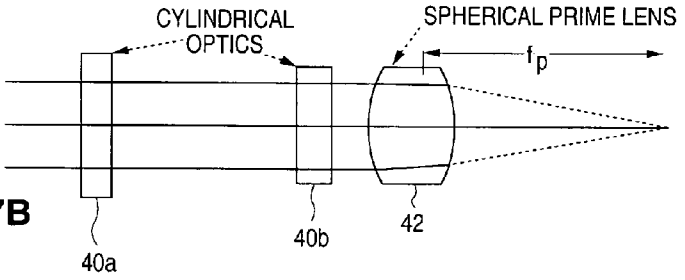

FIG. 17B

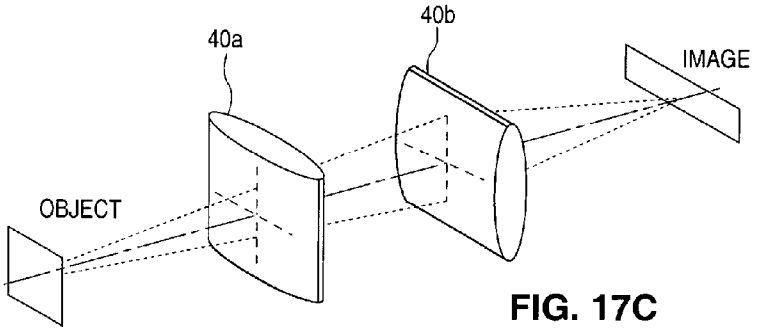

FIG. 17C

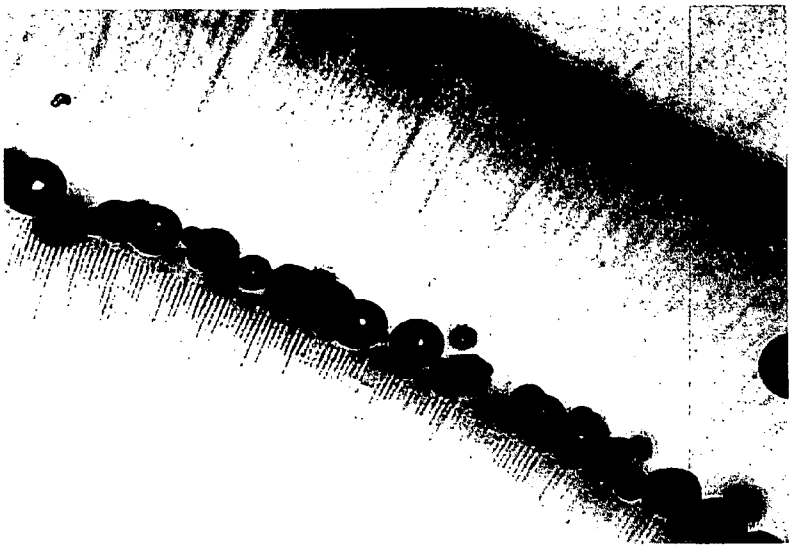

FIG. 20

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. In *Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. In *Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and

Richter, Chapter 44 of In *Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic. foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and

the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**, **2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**, **2**, **3**) focused with a set of lenses into multiple points (**1**, **2**, **3**) and thus producing plasma at different depths inside the tissue (**1**, **2**, **3**).

FIG. **9** is a diagram illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the

tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda(2.NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L\sim\lambda(4.NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial

length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of

cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device IO and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and

expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and

tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a*/b and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a*/b to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that

various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A system for cataract surgery on an eye of a patient, comprising:

a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure;

an optical coherence tomography (OCT) 3-Dimensional imaging system configured for imaging tissue of a cataractous crystalline lens of the patient;

an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens; and

a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically:

a) acquire image data from locations distributed throughout a volume of the cataractous crystalline lens using the imaging system;

b) construct one or more images of the patient's eye tissues from the image data, comprising an image of at least a portion of the crystalline lens;

c) construct an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and

d) operate the optical scanning system and laser assembly to direct a treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens.

2. The system of claim **1**, wherein the computer control system is programmed to effect an alignment step so as to align a treatment beam with a target tissue of the patient.

3. The system of claim **2**, wherein the alignment step comprises constructing an image of an alignment pattern on a tissue of the patient's eye.

4. The system of claim **3**, wherein the alignment step comprises adjusting the size, location or shape of the alignment pattern based on user input.

5. The system of claim **1**, wherein the posterior boundary does not transect the posterior capsule of the lens.

6. The system of claim **1**, wherein the computer control system is programmed to construct a lens fragmentation region comprising a posterior boundary that does not transect the posterior capsule of the lens.

7. The system of claim **6**, wherein the lens fragmentation region comprises a constructed anterior boundary and said posterior boundary of the lens fragmentation region.

8. The system of claim **6**, wherein the computer control system is programmed to operate the optical scanning system and the laser assembly so as to direct a treatment beam in a second pattern based on the fragmentation region so as to fragment the crystalline lens.

9. The system of claim **1**, wherein the computer control system is programmed to define a posterior axial cutting limit for positioning of any treatment beam focal zone, such that the posterior axial cutting limit is located anterior to the posterior capsule surface.

10. The system of claim **1**, wherein the computer control system is programmed to receive input from a user input interface and identify one or more parameters of the cataract surgery procedure based at least in part on the received user input.

11. A system for cataract surgery on an eye of a patient, comprising:

a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure;

an optical coherence tomography 3-Dimensional imaging system configured for imaging tissue of a cataractous crystalline lens of the patient;

an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens; and

a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically:

a) acquire image data from locations distributed throughout a volume of the crystalline lens using the imaging system;

b) identify one or more tissue structures of the cataractous crystalline lens based on the image data, the one or more structures comprising an anterior capsule boundary;

c) construct an anterior capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and

d) operate the optical scanning system and laser assembly to direct a treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens.

12. The system of claim **1**, wherein the computer control system is programmed to effect an alignment step so as to align a treatment beam with a target tissue of the patient.

13. The system of claim **11**, wherein the computer control system is programmed to construct one or more images of the patient's eye tissues from the image data, comprising an image of at least a portion of the crystalline lens.

14. The system of claim **11**, wherein the computer control system is programmed to: construct a lens fragmentation region comprising a posterior boundary that does not transect the posterior capsule of the lens; and operate the optical scanning system and the laser assembly so as to direct a treatment beam in a second pattern based on the fragmentation region so as to fragment the crystalline lens.

15. The system of claim **14**, wherein the computer control system is programmed to define a posterior axial cutting limit for positioning of any treatment beam focal zone, such that the posterior axial cutting limit is located anterior to the posterior capsule surface.

16. The system of claim **11**, further comprising a user input system for receiving input from a user comprising data that at least partially defines the one or more cutting regions.

17. A system for cataract surgery on an eye of a patient, comprising:

a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure;

an optical coherence tomography 3-Dimensional imaging system configured for imaging tissue of a cataractous crystalline lens of the patient;

an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens; and

a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically:

a) scan the patient's eye tissues with the imaging system so as to acquire image data of at least a portion of the crystalline lens;

b) construct one or more images of the patient's eye tissues from the image data, comprising an image of at least a portion of the crystalline lens;

c) construct an anterior capsulotomy cutting region based on the image data comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule;

d) construct a lens fragmentation region comprising a posterior boundary that does not transect the posterior capsule of the lens;

e) operate the optical scanning system and laser assembly to direct a treatment beam in a first pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens; and

f) operate the optical scanning system and the laser assembly to direct a treatment beam in a second pattern based on the fragmentation region so as to fragment the crystalline lens.

18. The system of claim **17**, wherein the computer control system is programmed to effect an alignment step so as to align a treatment beam with a target tissue of the patient, the alignment step comprising constructing an image of an alignment pattern on a tissue of the patient's eye.

19. The system of claim **17**, wherein the computer control system is programmed to define a posterior axial cutting limit for positioning of any treatment beam focal zone, such that the posterior axial cutting limit is located anterior to the posterior capsule surface.

20. The system of claim **17**, further comprising a user input system.

21. A system for cataract surgery on an eye of a patient, comprising:

a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure;

a 3-dimensional (3-D) imaging system configured for imaging tissue of a cataractous crystalline lens of the patient;

an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens; and

a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically:

a) acquire image data of the crystalline lens using the imaging system;

b) identify one or more tissue structures of the cataractous crystalline lens based on the image data, the one or more structures comprising an anterior capsule portion;

c) construct a cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule, wherein the posterior cutting boundary is anterior to a posterior capsule of the lens;

d) operate the optical scanning system and laser assembly based on the constructed cutting region so as to direct a treatment beam in a first cutting pattern so as to create an anterior capsulotomy in the anterior capsule portion of the lens; and

e) operate the optical scanning system and laser assembly based on the constructed cutting region so as to direct a treatment beam in a second cutting pattern so as to effect cutting of cataractous lens tissue of the cutting region into a plurality of patterned segments or fragmented pieces for subsequent removal.

22. The system of claim **21**, wherein constructing the cutting region comprises constructing an anterior capsulotomy cutting region and a lens segmentation or fragmentation region.

23. The system of claim **21**, wherein one or more of the plurality of segments or fragmented pieces comprise a length of at least 1 mm.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,403,921 B2
APPLICATION NO. : 13/587833
DATED : March 26, 2013
INVENTOR(S) : Daniel V. Palanker et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page, at item (12) Inventors: Please replace "Palankar et al." with "Palanker et al."

On the Title Page, at item (75) Inventors: Please replace "Daniel V. Palankar" with "Daniel V. Palanker"

Signed and Sealed this
Twenty-third Day of April, 2013

Teresa Stanek Rea
Acting Director of the United States Patent and Trademark Office

EXHIBIT C

US008425497B2

(12) **United States Patent**
Blumenkranz et al.

(10) **Patent No.: US 8,425,497 B2**
(45) **Date of Patent: *Apr. 23, 2013**

(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

(75) Inventors: **Mark S. Blumenkranz**, Portola Valley, CA (US); **Daniel V. Palanker**, Sunnyvale, CA (US); **David H. Mordaunt**, Los Gatos, CA (US); **Dan E. Andersen**, Menlo Park, CA (US)

(73) Assignee: **Optimedica Corporation**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/072,652**

(22) Filed: **Mar. 25, 2011**

(65) **Prior Publication Data**

US 2011/0178511 A1 Jul. 21, 2011

Related U.S. Application Data

(63) Continuation of application No. 11/328,970, filed on Jan. 9, 2006, now Pat. No. 8,394, 084.

(60) Provisional application No. 60/643,056, filed on Jan. 10, 2005.

(51) **Int. Cl.**
A61B 18/18 (2006.01)

(52) **U.S. Cl.**
USPC **606/4**; 606/5

(58) **Field of Classification Search** 606/4, 5, 606/11, 12, 16
See application file for complete search history.

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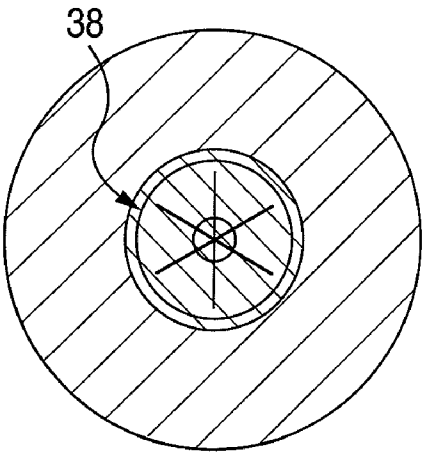
Primary Examiner — Bill Thomson
Assistant Examiner — Jeffrey Lipitz
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye tissue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

19 Claims, 10 Drawing Sheets



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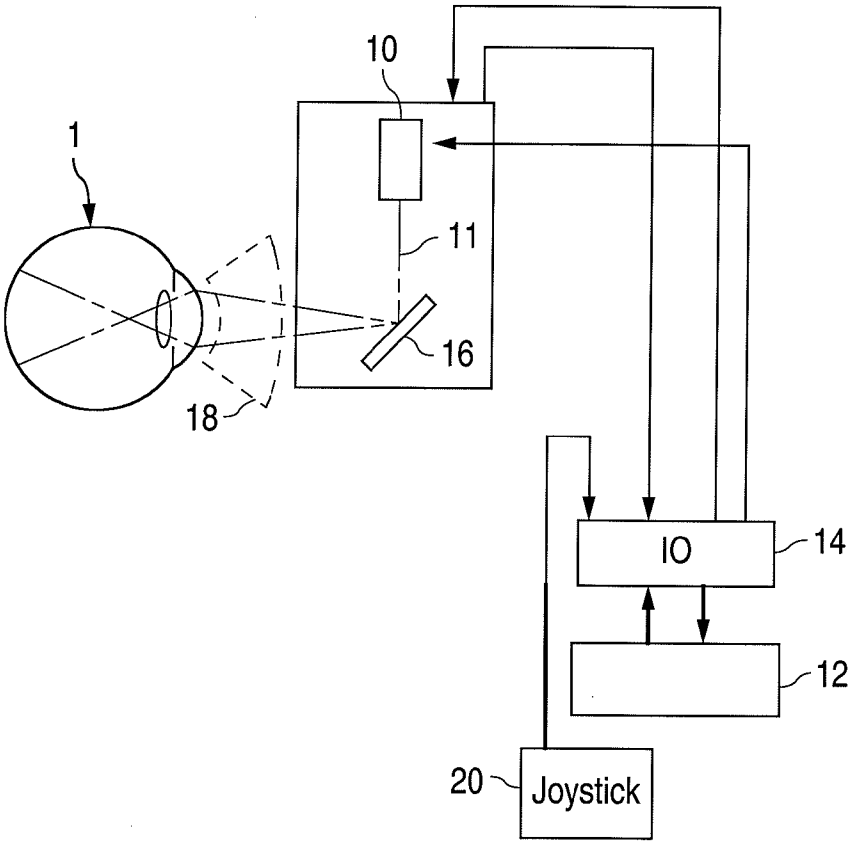

FIG. 1

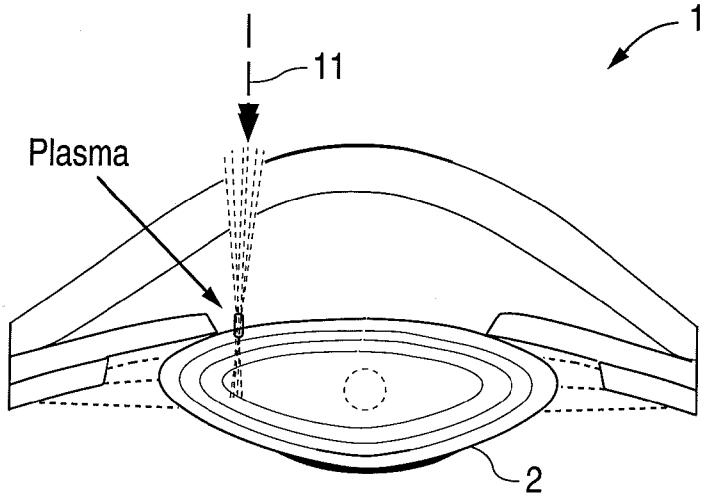

FIG. 2

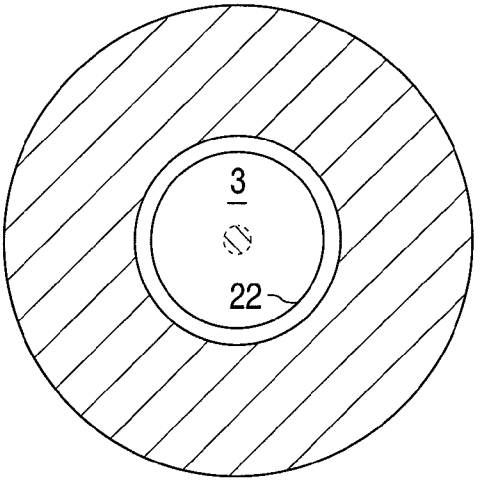

FIG. 3

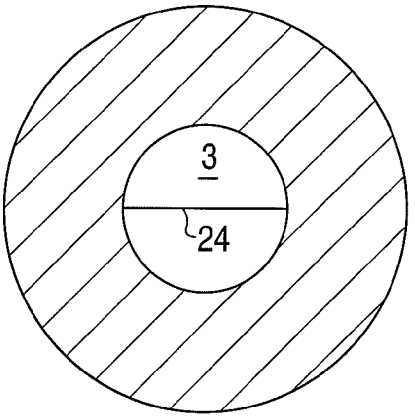

FIG. 4

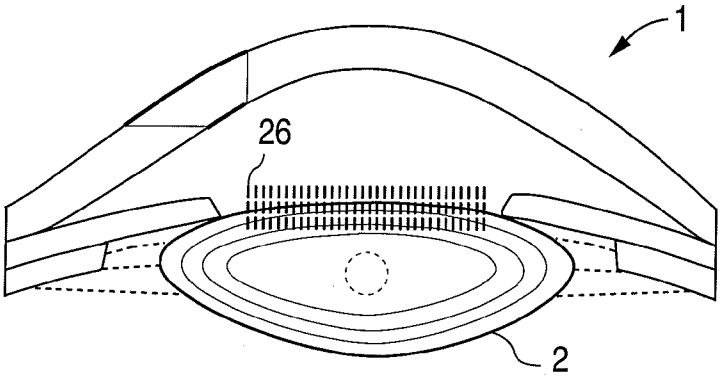

FIG. 5

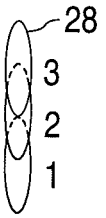

FIG. 6

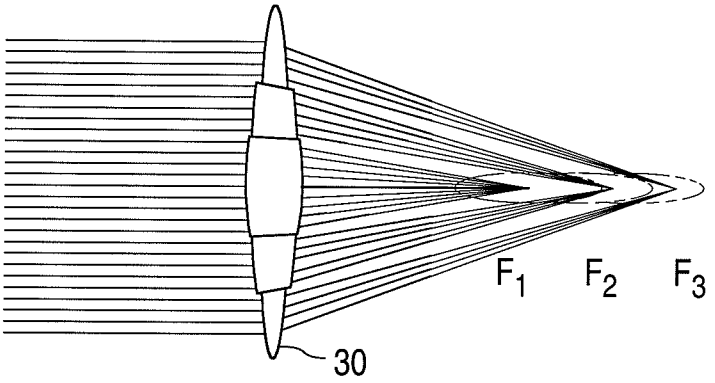

FIG. 7A

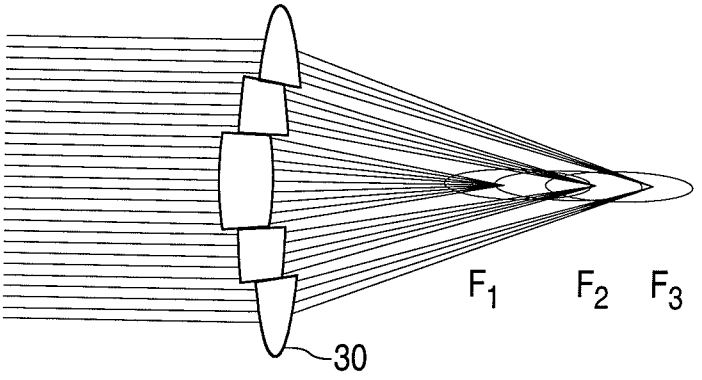

FIG. 7B

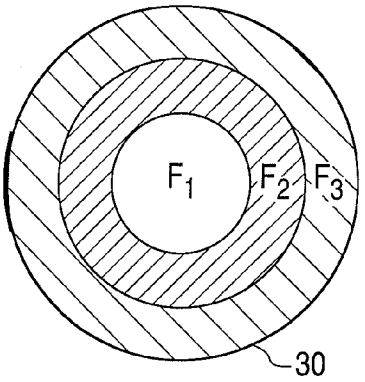

FIG. 7C

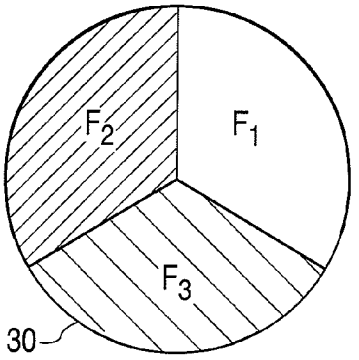

FIG. 7D

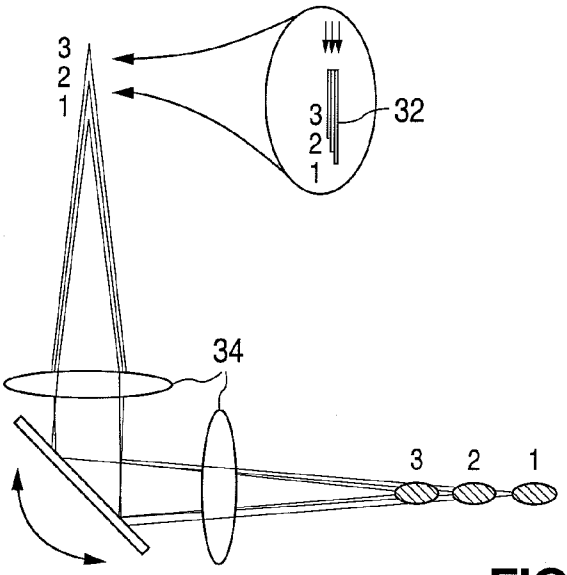

FIG. 8

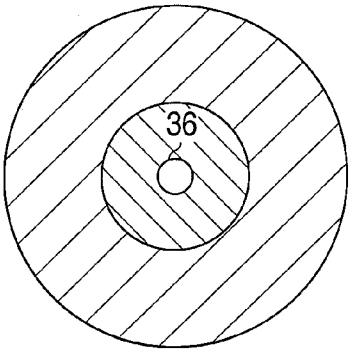

FIG. 9A

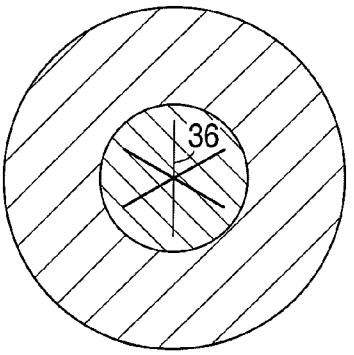

FIG. 9B

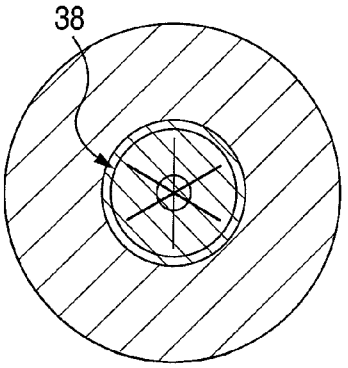

FIG. 10A

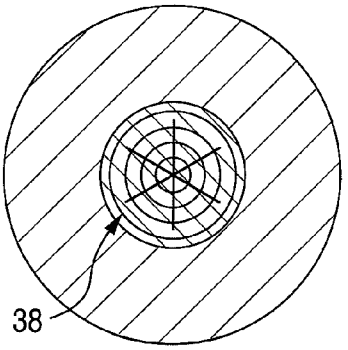

FIG. 10B

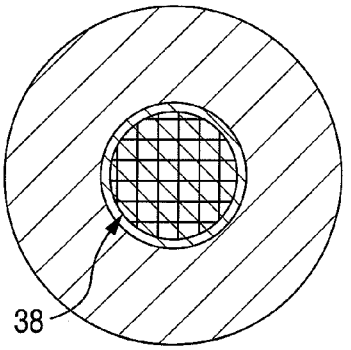

FIG. 10C

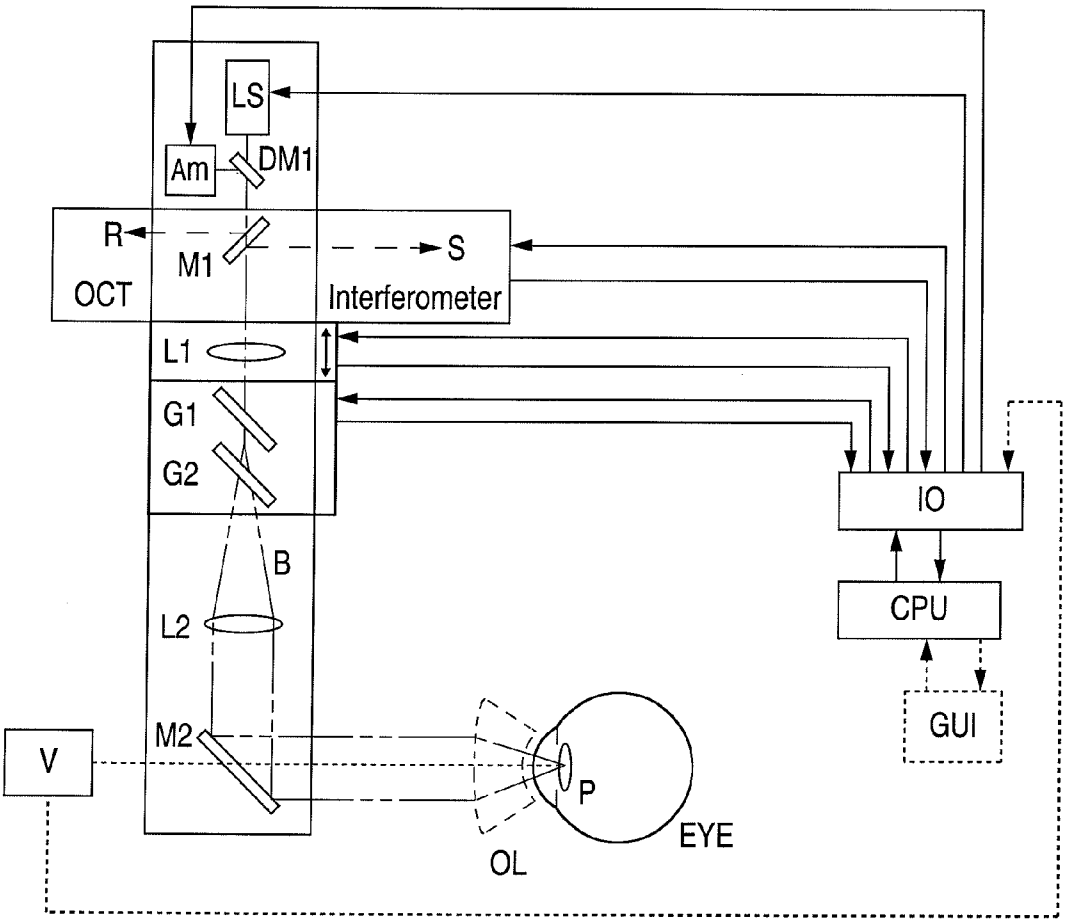

FIG. 11

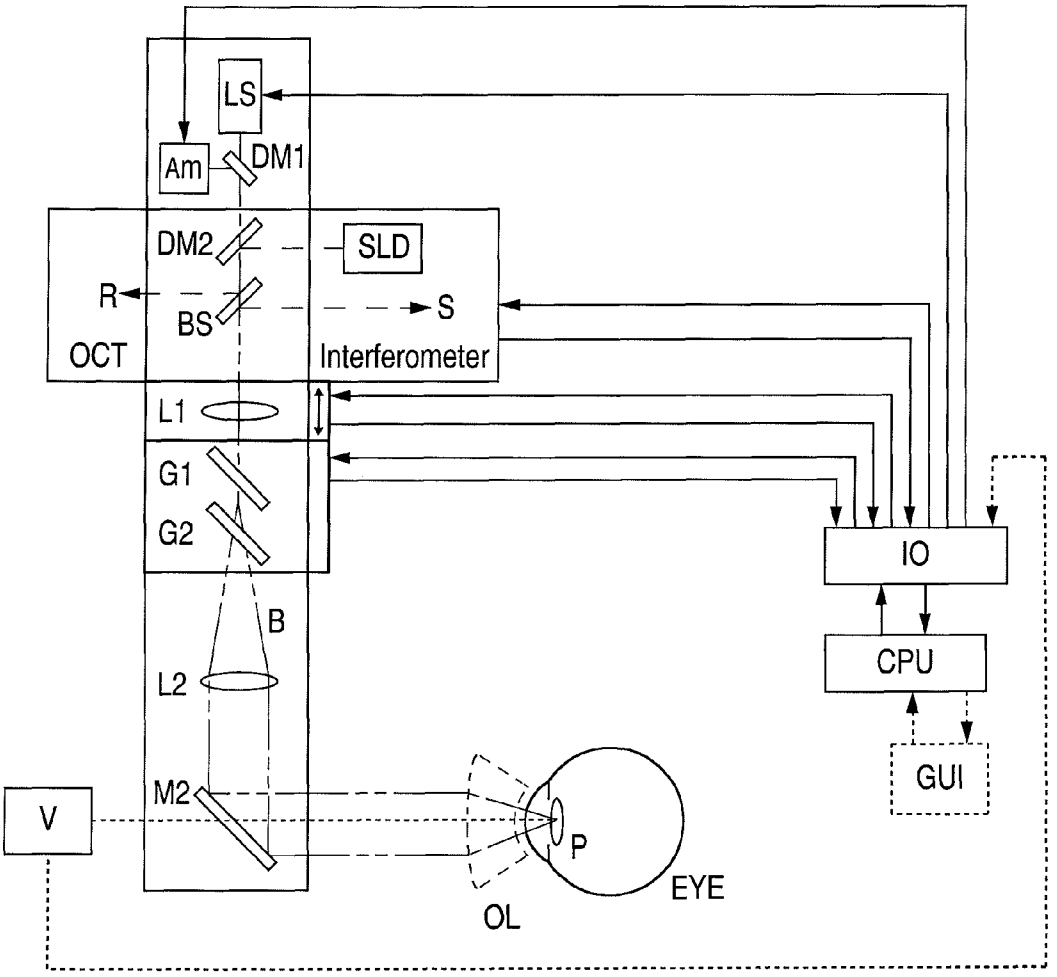
LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

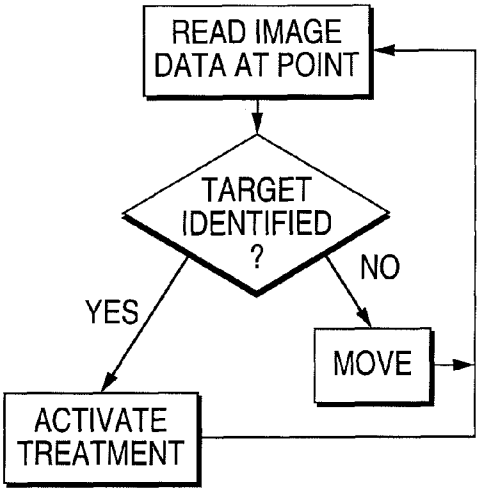
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

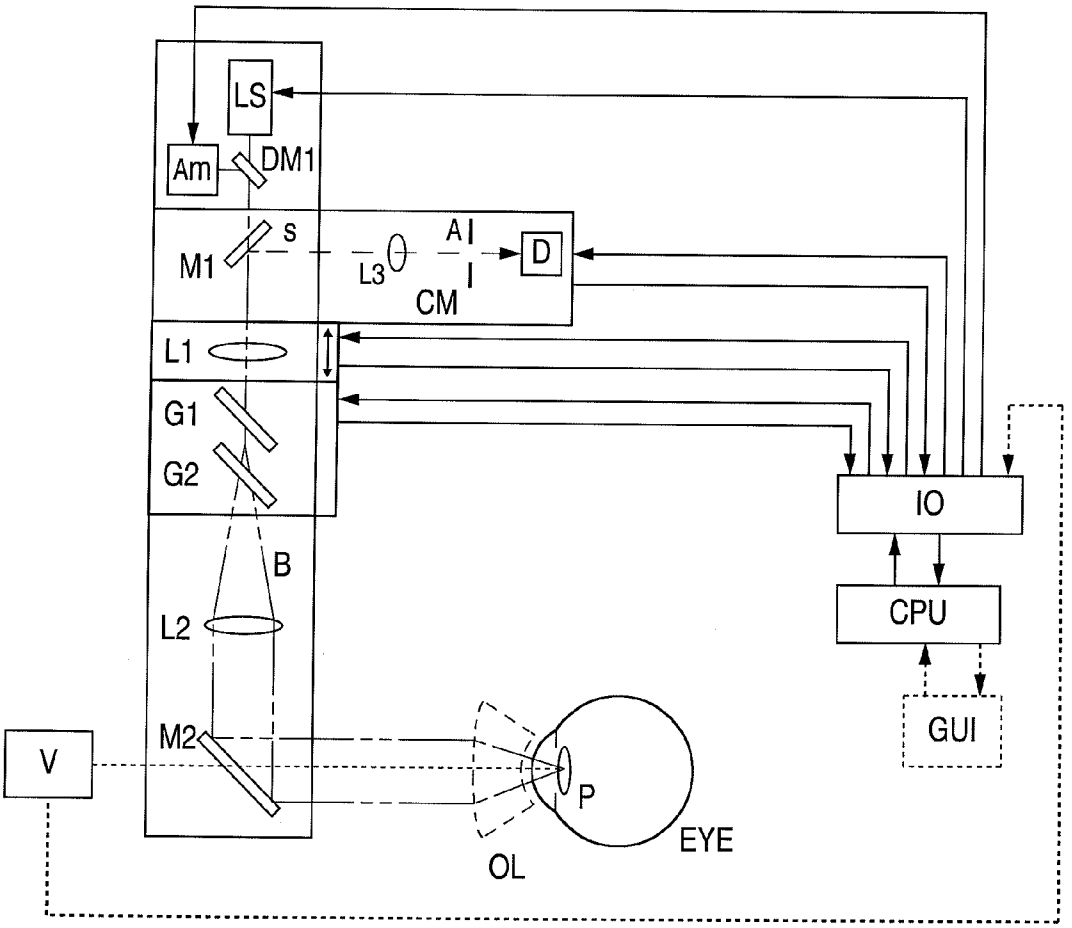

FIG. 13

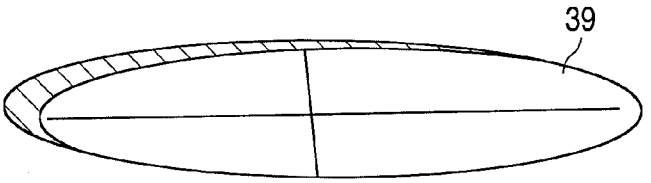

FIG. 16

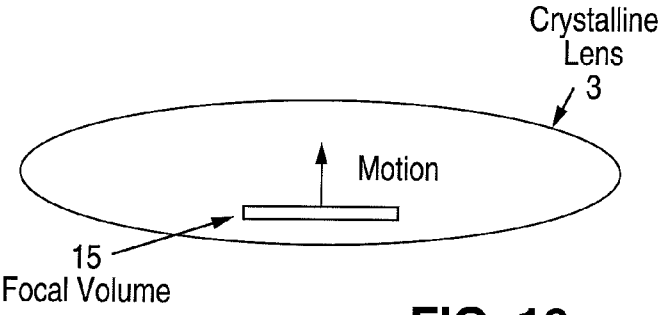

FIG. 19

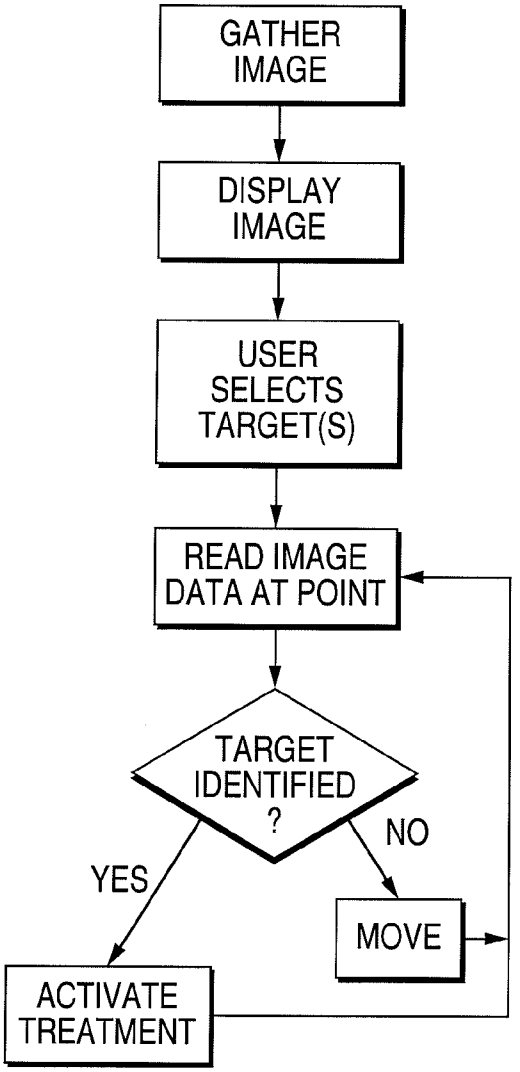
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

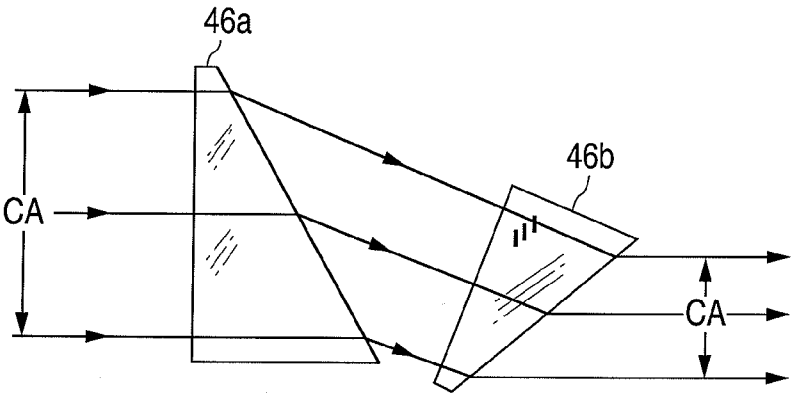
46a
46b
CA
CA

FIG. 18

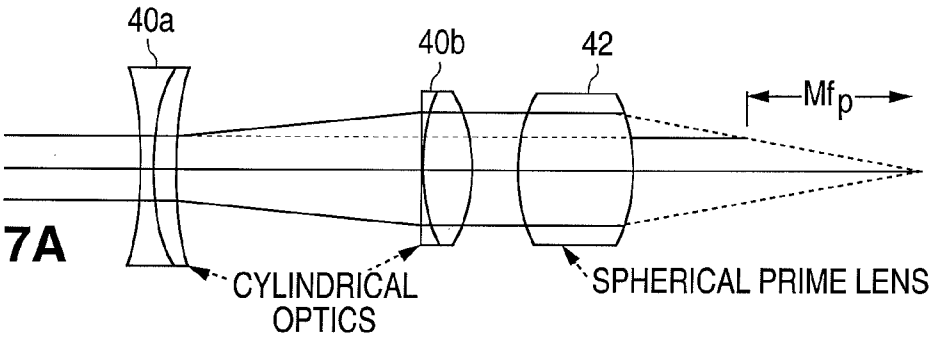

FIG. 17A

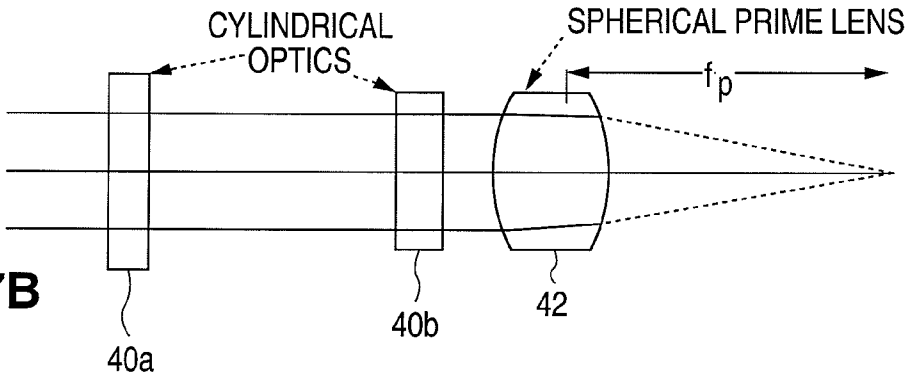

FIG. 17B

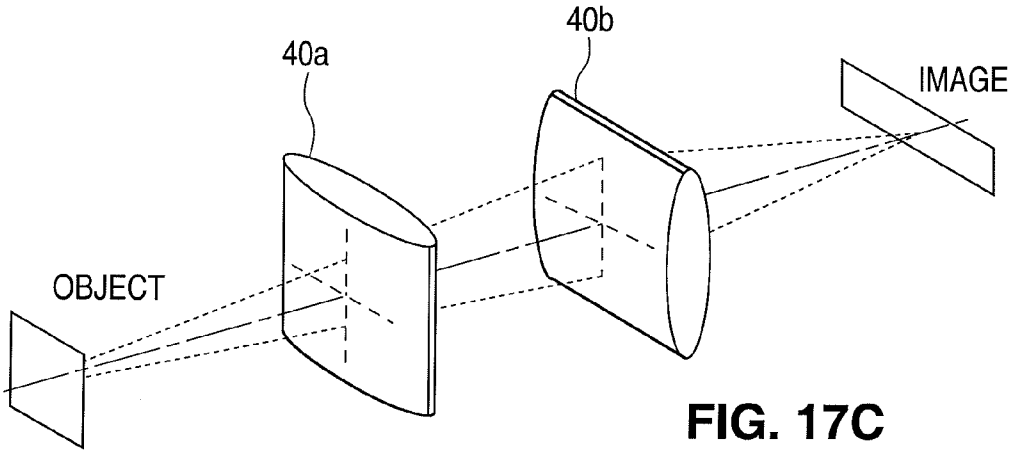

FIG. 17C

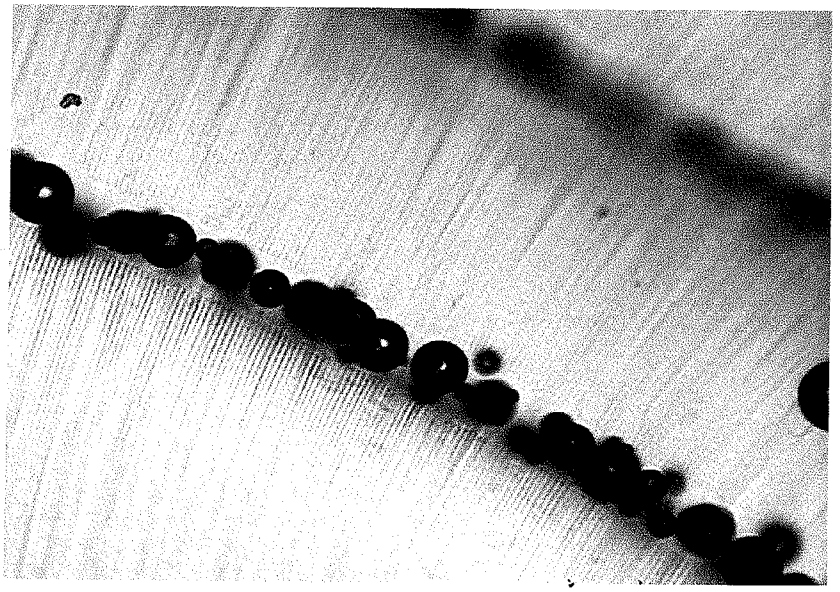

FIG. 20

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

RELATED APPLICATION DATA

This application is a continuation of U.S. application Ser. No. 11/328,970, filed Jan. 9, 2006 now U.S. Pat. No. 8,394,084, which claims the benefit under 35 U.S.C. §119 of U.S. Provisional Application No. 60/643,056, filed Jan. 10, 2005. The foregoing applications are each hereby incorporated by reference into the present application in their entirety.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. Journal of Cataract and Refractive Surgery 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina

by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. In Cataract Surgery Techniques Complications and Management. 2.sup.nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. In Cataract Surgery Techniques Complications and Management. 2.sup.nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is

illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of In Cataract Surgery Techniques Complications and Management. 2.sup.nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second

pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**, **2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**,**2**,**3**) focused with a set of lenses into multiple points (**1**,**2**,**3**) and thus producing plasma at different depths inside the tissue (**1**,**2**,**3**).

FIG. **9** is a diagram illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters: [0047] 1) pulse energy up to 1 .mu.J, repetition rate up to 1 MHz, pulse duration <1 ps [0048] 2) pulse energy up to 10 .mu.J, rep. rate up to 100 kHz, pulse duration <1 ps. [0049] 3) Pulse energy up to 1000 .mu.J, rep rate up to 1 kHz, pulse duration <3 ps. Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 .mu.J, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by d=.lamda.F/D.sub.b, where F is the focal length of the last focusing element, D.sub.b is the beam diameter on the last lens, and .lamda. is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D.sub.b=10 mm, and wavelength .lamda.=1.04 um, the focal spot diameter will be d.apprxeq..lamda./(2NA).apprxeq..lamda.F/D.sub.b=15 .mu.m, where the numerical aperture of the focusing optics, NA.apprxeq.D.sub.b/(2F).

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 .mu.m (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy

circle being D.sub.c=8 mm, the number of required pulses will be: N=.pi.D.sub.c/R=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 .mu.m), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 .mu.m the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about .PHI.=100J/cm.sup.2. With a focal spot diameter being d=15 .mu.m, the threshold pulse energy will be E.sub.th=.PHI.*.pi.d.sup.2/4=176 .mu.J. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 .mu.J. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E.sub.b=35 .mu.J. This corresponds to a bubble diameter d b=6 .times. E b .pi. .times. .times. P a 3=48 .times. .times. .mu. .times. .times. m.

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, .PHI., for dielectric breakdown for 100 fs is about .PHI.=2J/cm.sup.2; for 1 ps it is .PHI.=2.5 J/cm.sup.2. Using the above pulse durations, and a focal spot diameter d=15 .mu.m, the threshold pulse energies will be E.sub.th=.PHI.*.pi.d.sup.2/4=3.5 and 4.4 .mu.J for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E.sub.th=7 and 9 .mu.J, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D.sub.b=10 mm, to provide focusing into a spot of about 4 .mu.m in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 .mu.J, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured .about.10 .mu.m in diameter, and .about.100 .mu.m in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: L.about..lamda./(4NA.sup.2)=dF/D.sub.b. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D.sub.b=10 mm, and focal spot diameter d=15 .mu.m, the laser beam waist half-length L would be 240 .mu.m.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example: [0062] 1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also

helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 .mu.J. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F.sub.1, F.sub.2, F.sub.3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**. Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device I**0** and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO Graphical user interface

GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorp-

tion band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6.times.6.times.4 mm=144 mm.sup.3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E.sub.1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1.times.1 mm plane will require 66.times.66=4356 pulses. The 2 side walls will require 2.times.66.times.5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT =(E.sub.1*N)/pcV=50.16 mJ/(4.19 mJ/K) =12 K. This will lead to maximal temperature T=37+12.degree. C.=49.degree. C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6.degree. C. (T=43.degree. C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1.times.1.times.4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E.sub.1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D.sub.b=10 mm would allow for focusing into a spot of about

4 .mu.m in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm.sup.2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 .mu.J, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm.sup.2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens +1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t.sub.pulse<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

The invention claimed is:

1. A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:

operating an imaging system, coupled to an electronics control system comprising a computer, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images include an image of at least a portion of the crystalline lens;

identifying, using the control system, a cutting region based on the image data, the cutting region being at least partially defined by an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens;

generating a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the crystalline lens into a plurality of pieces for subsequent removal, the segmentation of the crystalline lens including:

focusing the beam at a first focal point located at a first depth in the eye tissue;

scanning the beam on the eye while focused at the first depth so as to create an incision pattern within the cutting region at the first depth;

focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth; and

scanning the beam on the eye while focused at the second depth so as to create an incision pattern within the cutting region at the second depth.

2. The method of claim **1**, wherein the imaging system is an optical coherence tomography system.

3. The method of claim **1**, further comprising aligning an aiming beam with a target tissue of the patient's eye prior to incising the eye tissue within the cutting region.

4. The method of claim **3**, wherein the aligning comprises generating an image of an alignment pattern on a tissue of the patient's eye.

5. The method of claim **4**, wherein the aligning comprises adjusting at least one of size, location, or shape of the alignment pattern based on user input.

6. The method of claim **1**, wherein the cutting region does not transect the posterior capsule.

7. The method of claim **1**, wherein all laser cutting occurs anterior to the posterior capsule.

8. The method of claim **1**, further comprising entering user input to an interface so as to identify one or more parameters used in incising the eye tissue.

9. The method of claim **1**, further comprising scanning the beam on the eye so as to incise an opening in the anterior capsule.

10. The method of claim **1**, further comprising scanning the beam on the eye so as to incise an opening in the posterior capsule.

11. The method of claim **1**, further comprising identifying one or more boundaries of tissue structures of the eye that are selected from the group consisting of: an anterior corneal surface, a posterior corneal surface, an iris, and a pupil.

12. The method of claim **1**, wherein the imaging system includes at least one of a camera, an interferometer, an optical coherence tomography system, a time domain optical coherence tomography system, a frequency domain optical tomography system, a confocal microscope, and a scanning confocal microscope.

13. The method of claim **1**, wherein an incision pattern is selected from the group consisting of: two or more intersecting straight lines, a crosshatched pattern comprising two or more sets of intersecting lines, one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines.

14. The method of claim **1**, wherein the lens is fragmented into segments that can be removed through a lumen of an ophthalmic aspiration probe.

15. The method of claim **1**, further comprising receiving input from an operator regarding one or more parameters of the two-dimensional incision pattern.

16. A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:

operating an optical coherence tomography imaging system, coupled to an electronics control system comprising a computer, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient and construct one or more images of at least a portion of the crystalline lens from the image data;

identifying, using the control system, a cutting region based on the image data, the cutting region being at least partially defined by an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens, wherein the posterior cutting boundary is disposed anterior to the lens posterior capsule;

generating a beam of light using a pulsed laser system controlled by the control system, wherein the pulsed laser system is guided by the control system based in part on the image data so as to scan a focal zone of the beam in a pattern in the lens for 3-dimensional patterned laser cutting and segmentation of the crystalline lens within the cutting region into a plurality of pieces for subsequent removal.

17. A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:

operating an imaging system, coupled to an electronics control system comprising a computer, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient for constructing one or more images of at least a portion of the crystalline lens from the image data;

identifying, using the control system, a cutting region based on the image data, the cutting region having an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens, wherein the posterior cutting boundary is disposed anterior to the lens posterior capsule;

generating a beam of light using a pulsed laser system controlled by the control system, wherein the pulsed laser system is guided by the control system based at least in part on the image data so as to scan a focal zone of the beam in a pattern to effect 3-dimensional patterned laser cutting of the crystalline lens within the cutting region into a plurality of segments or pieces for subsequent removal.

18. The method of claim **17**, comprising scanning a beam of the pulsed laser system in a capsulotomy pattern so as to effect an opening in the anterior capsule prior to the segmentation of the crystalline lens.

19. The method of claim **17**, wherein the patterned pieces are cut so as to have a length of 1 mm or larger.

* * * * *

EXHIBIT D

US008500724B2

(12) **United States Patent**
Blumenkranz et al.

(10) **Patent No.: US 8,500,724 B2**
(45) **Date of Patent: *Aug. 6, 2013**

(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

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(73) Assignee: **Optimedica Corporation**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/072,646**

(22) Filed: **Mar. 25, 2011**

(65) **Prior Publication Data**

US 2011/0178512 A1 Jul. 21, 2011

Related U.S. Application Data

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(60) Provisional application No. 60/643,056, filed on Jan. 10, 2005.

(51) **Int. Cl.**
A61B 18/20 (2006.01)

(52) **U.S. Cl.**
USPC **606/5**; 606/6

(58) **Field of Classification Search**
USPC 606/4, 5, 11, 12, 16
See application file for complete search history.

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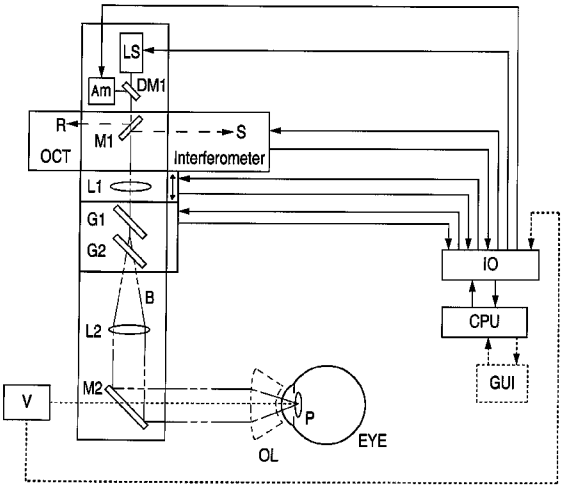
(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye tissue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

23 Claims, 10 Drawing Sheets



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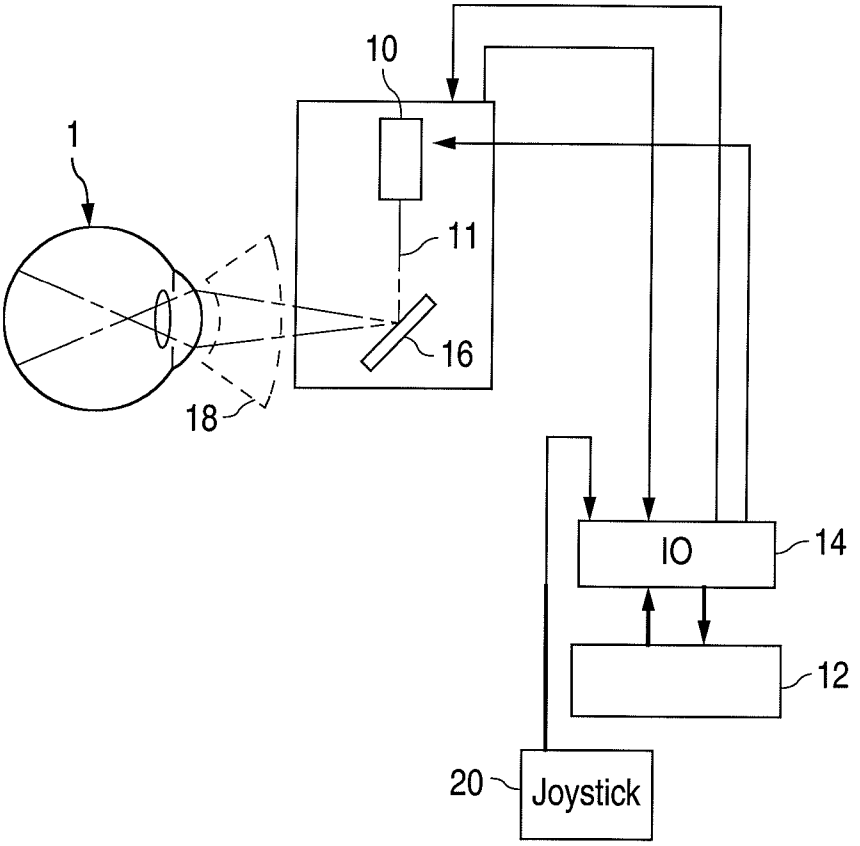
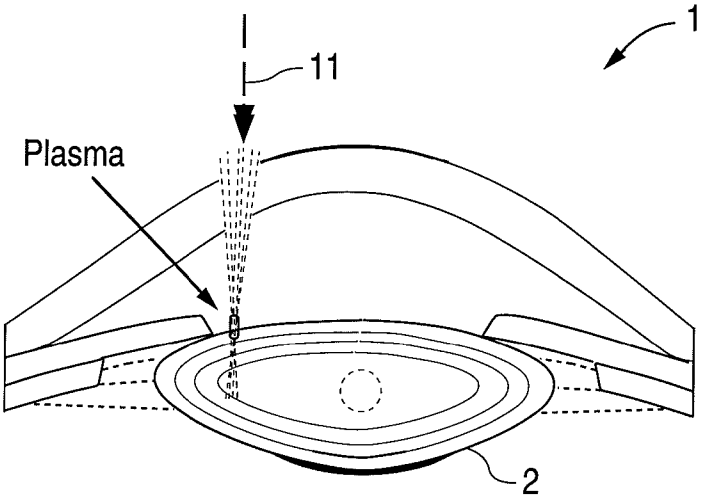


FIG. 1



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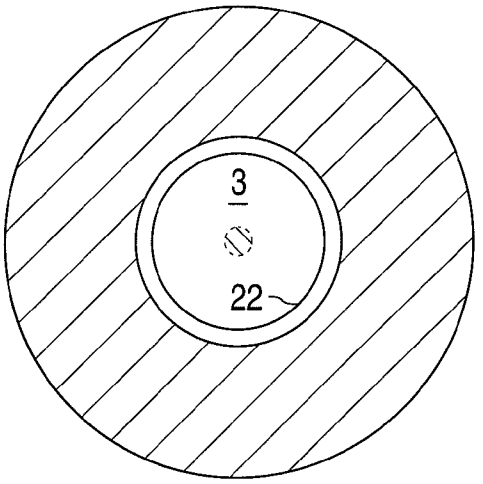

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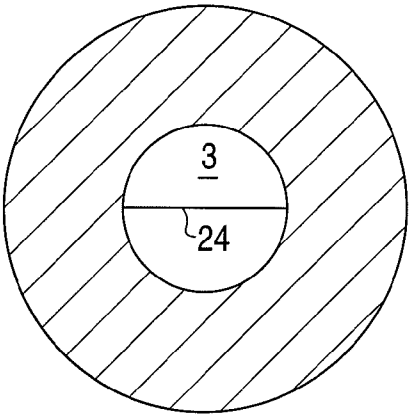
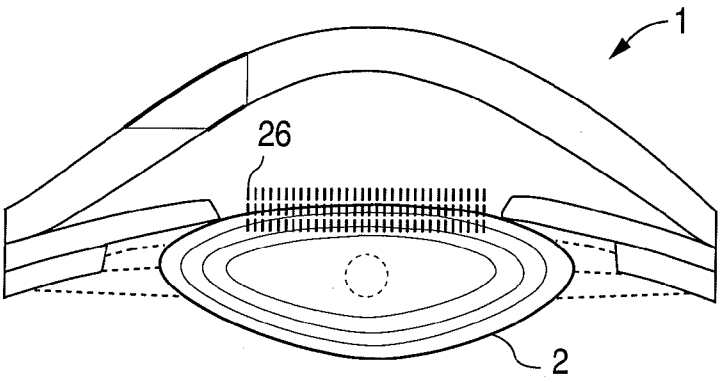


FIG. 4



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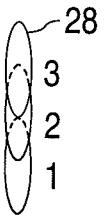


FIG. 6

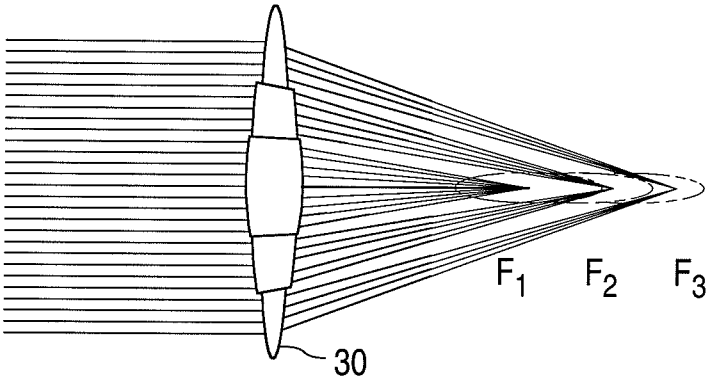


FIG. 7A

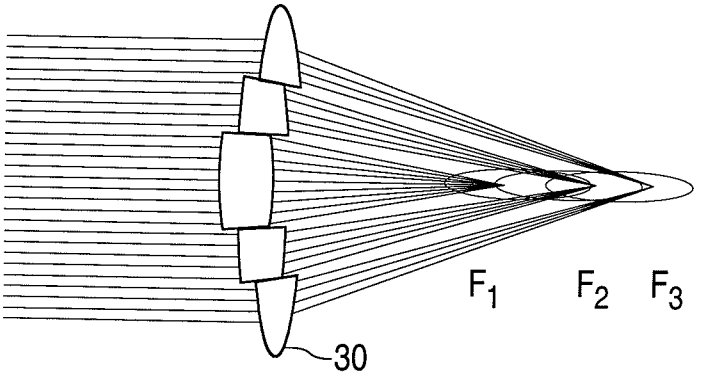
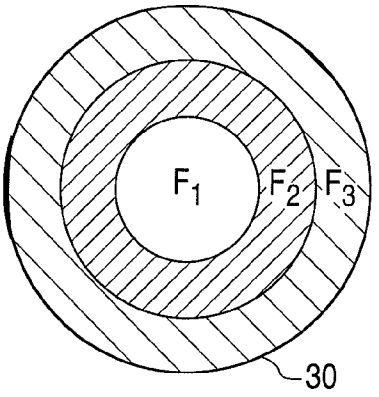


FIG. 7B



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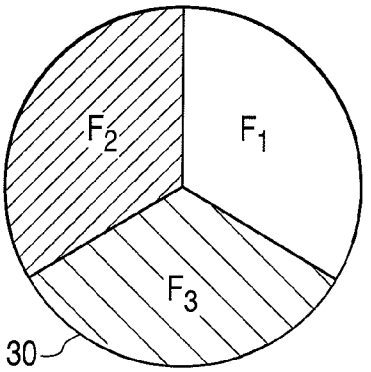

FIG. 7D

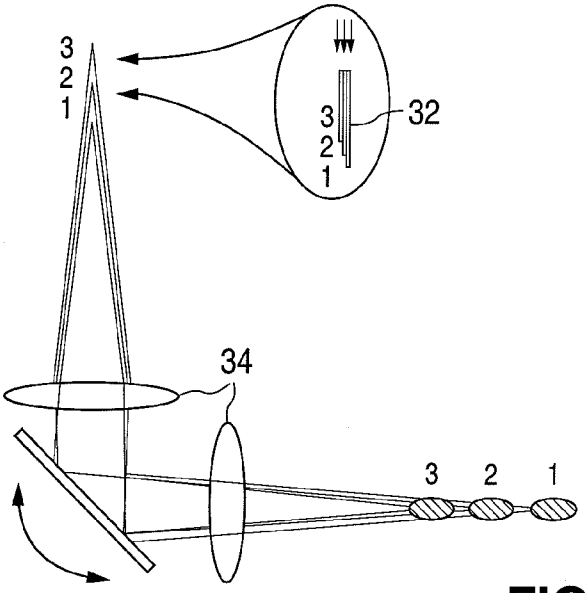

FIG. 8

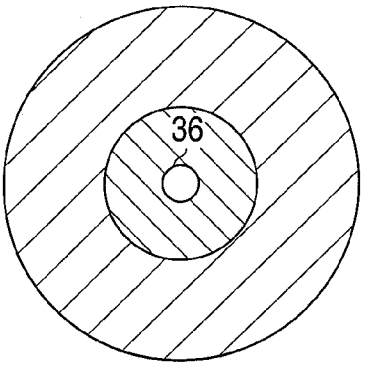

FIG. 9A

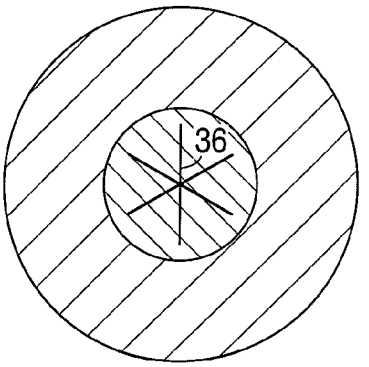

FIG. 9B

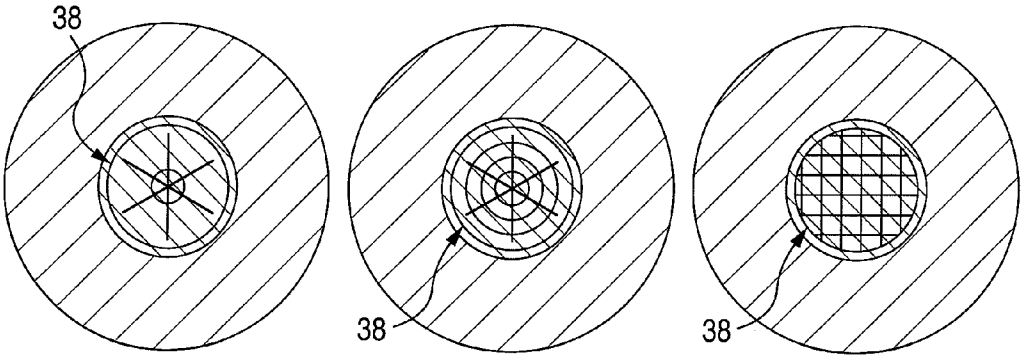

FIG. 10A FIG. 10B FIG. 10C

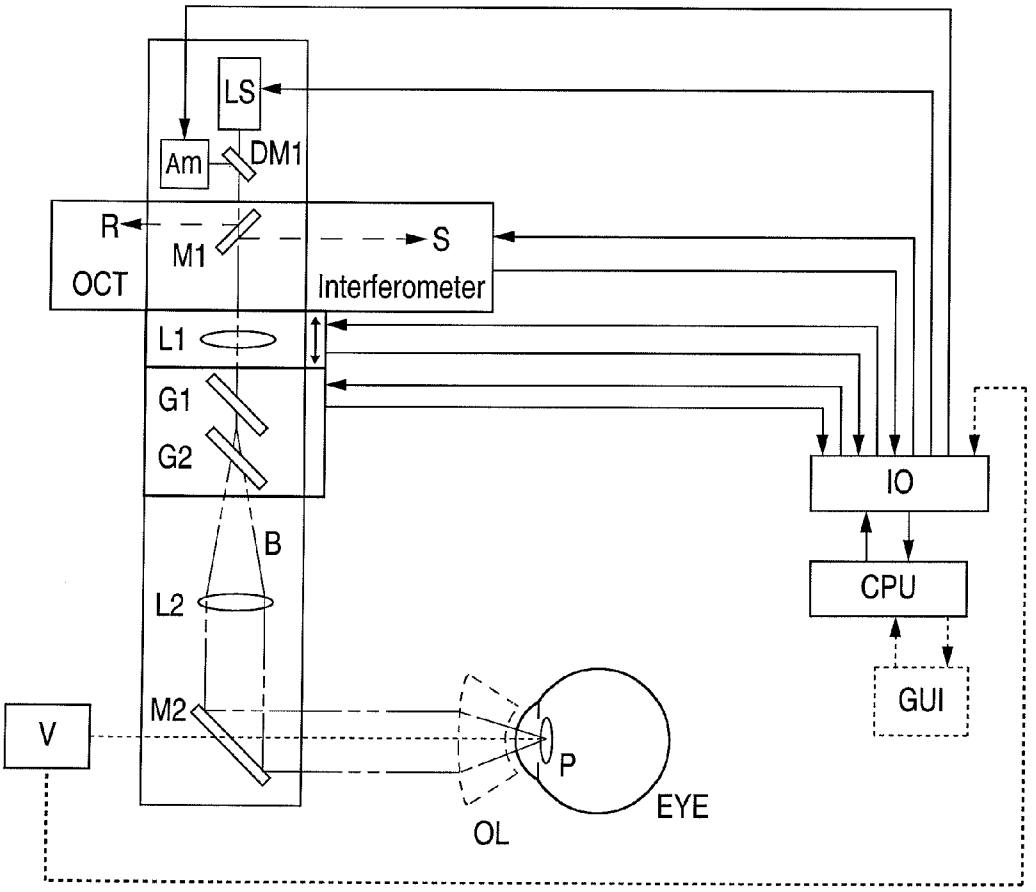

FIG. 11

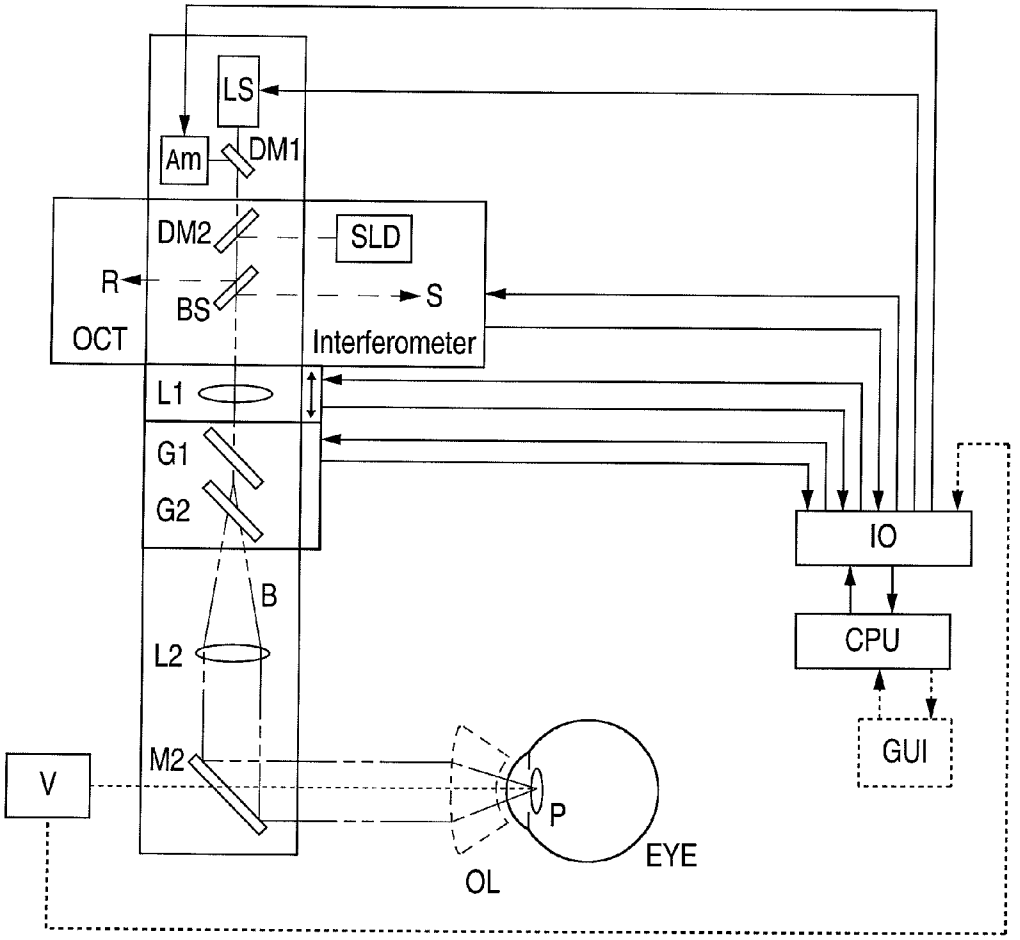
LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

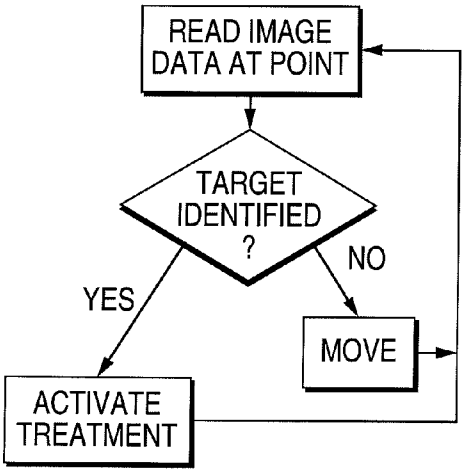
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

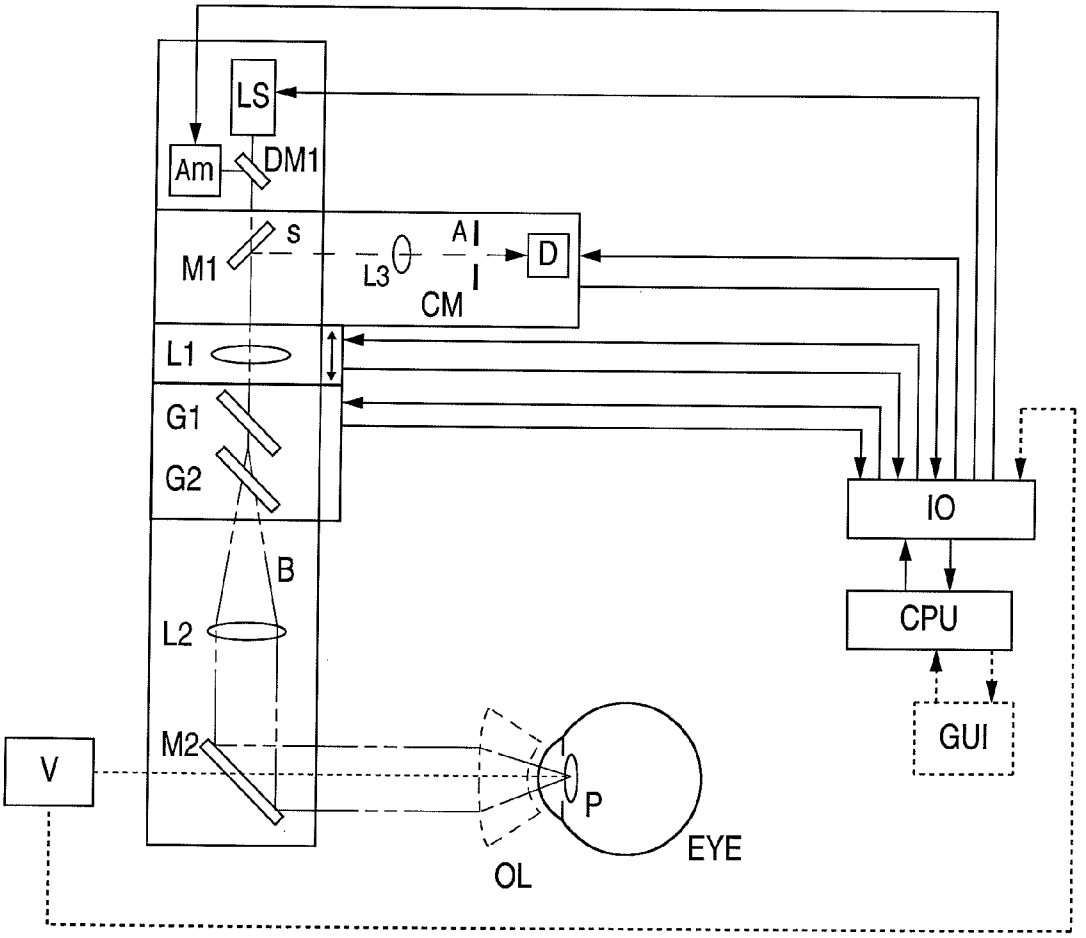

FIG. 13

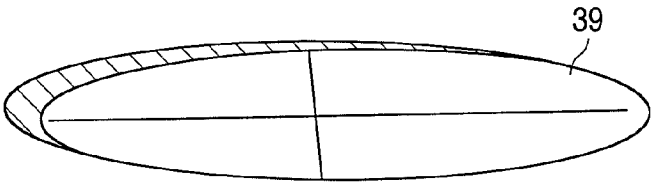

FIG. 16

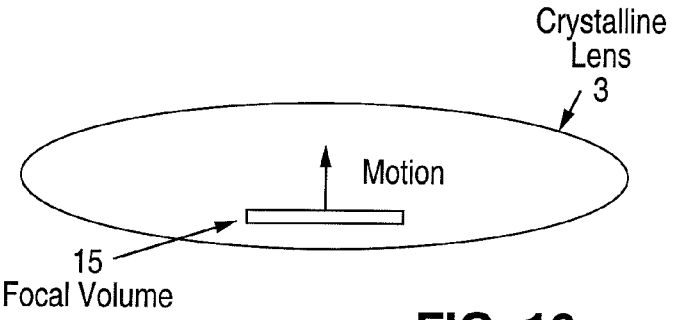

FIG. 19

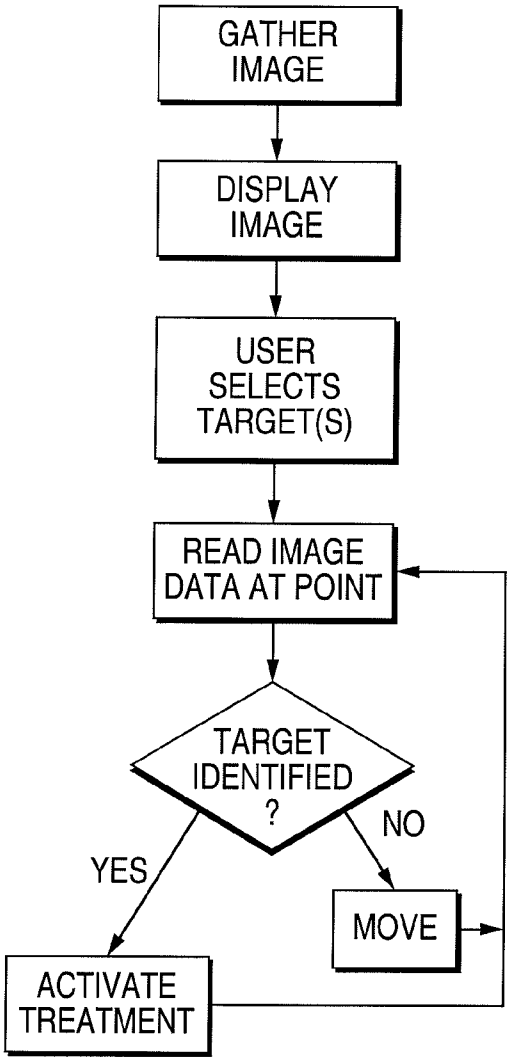
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

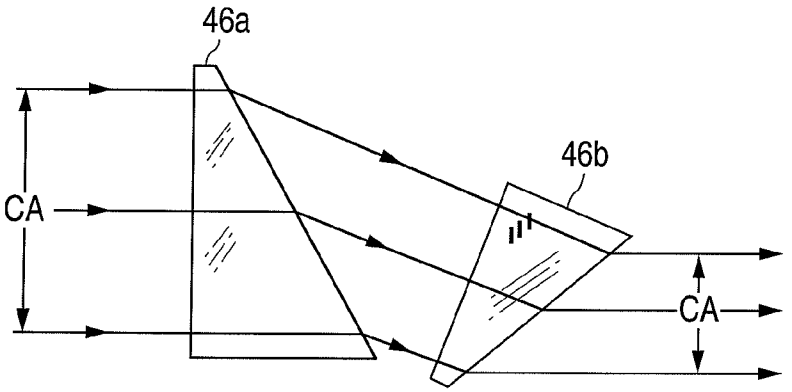
46a
46b
CA
CA

FIG. 18

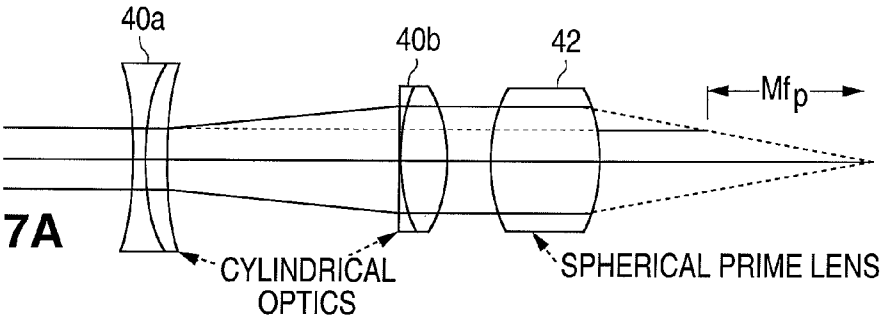

FIG. 17A

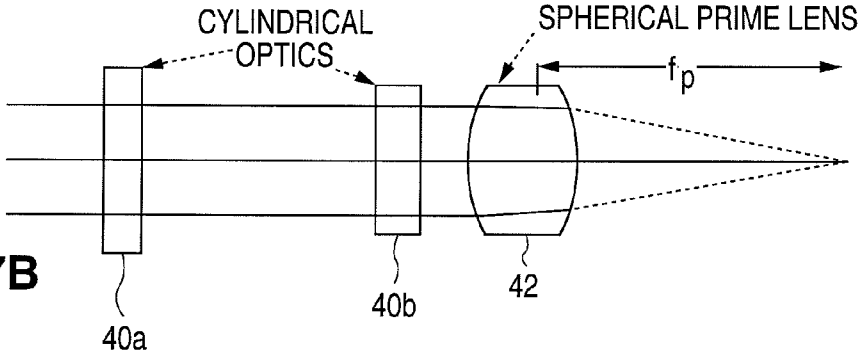

FIG. 17B

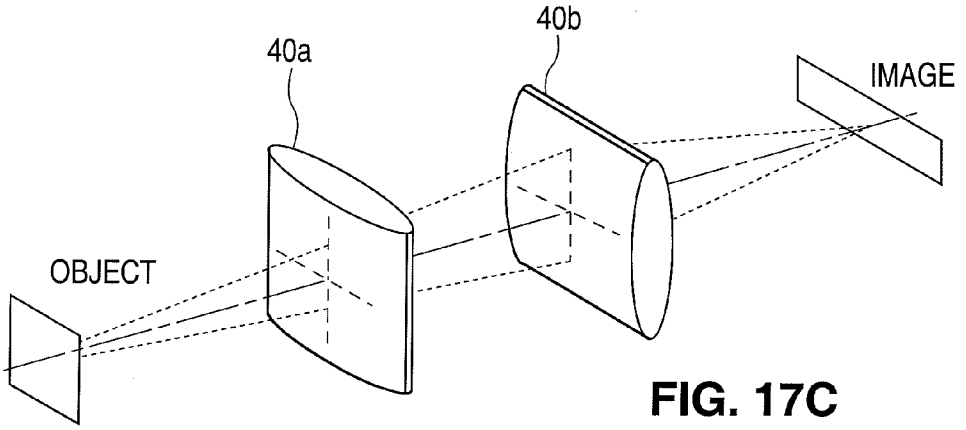

FIG. 17C

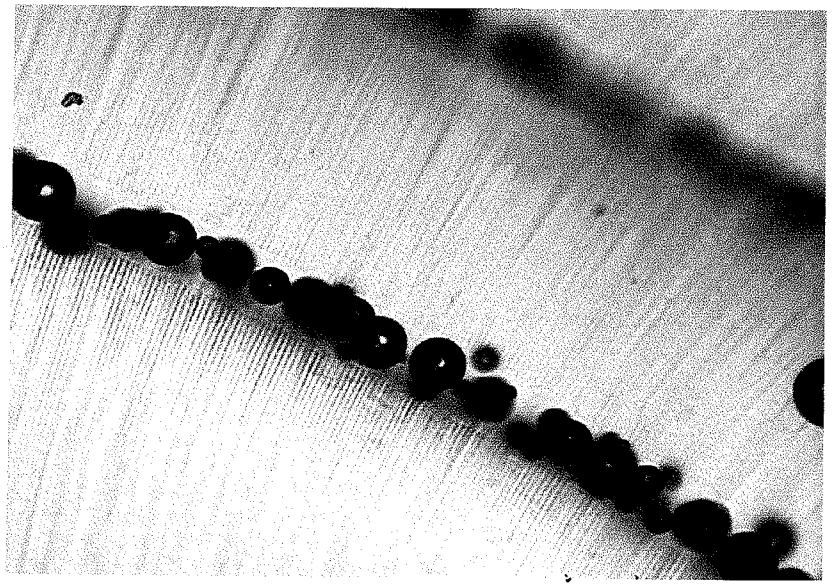

FIG. 20

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

RELATED APPLICATION DATA

This application is a continuation of U.S. application Ser. No. 11/328,970, filed Jan. 9, 2006 now U.S. Pat. No. 8,394,084 , which claims the benefit under 35 U.S.C. §119 of U.S. Provisional Application No. 60/643,056, filed Jan. 10, 2005. The foregoing applications are each hereby incorporated by reference into the present application in their entirety.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. Journal of Cataract and Refractive Surgery 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. In Cataract Surgery Techniques Complications and Management. 2.sup.nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. In Cataract Surgery Techniques Complications and Management. 2.sup.nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is

illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of In Cataract Surgery Techniques Complications and Management. 2.sup.nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second

pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**,**2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**,**2**,**3**) focused with a set of lenses into multiple points (**1**,**2**,**3**) and thus producing plasma at different depths inside the tissue (**1**,**2**,**3**).

FIG. **9** is a diagram illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters: 1) pulse energy up to 1 .mu.J, repetition rate up to 1 MHz, pulse duration <1 ps 2) pulse energy up to 10 .mu.J, rep. rate up to 100 kHz, pulse duration <1 ps. 3) Pulse energy up to 1000 .mu.J, rep rate up to 1 kHz, pulse duration <3 ps. Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 .mu.J, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by d=.lamda.F/D.sub.b, where F is the focal length of the last focusing element, D.sub.b is the beam diameter on the last lens, and .lamda. is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D.sub.b=10 mm, and wavelength .lamda.=1.04 um, the focal spot diameter will be d.apprxeq..lamda./(2NA).apprxeq..lamda.F/D.sub.b=15 .mu.m, where the numerical aperture of the focusing optics, NA.apprxeq.D.sub.b/(2F).

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 .mu.m (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D.sub.c=8 mm, the number of required pulses

will be: N=.pi.D.sub.c/R=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 .mu.m), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 .mu.m the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about .PHI.=100 J/cm.sup.2. With a focal spot diameter being d=15 .mu.m, the threshold pulse energy will be E.sub.th=.PHI.*.pi.d.sup.2/4=176 .mu.J. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 .mu.J. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E.sub.b=35 .mu.J. This corresponds to a bubble diameter d b=6 .times. E b .pi. .times. .times. P a 3=48 .times. .times. .mu. .times. .times. m.

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, .PHI., for dielectric breakdown for 100 fs is about .PHI.=2 J/cm.sup.2; for 1 ps it is .PHI.=2.5 J/cm.sup.2. Using the above pulse durations, and a focal spot diameter d=15 .mu.m, the threshold pulse energies will be E.sub.th=.PHI.*.pi.d.sup.2/4=3.5 and 4.4 .mu.J for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E.sub.th=7 and 9 .mu.J, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D.sub.b=10 mm, to provide focusing into a spot of about 4 .mu.m in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 .mu.J, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured .about.10 .mu.m in diameter, and .about.100 .mu.m in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: L.about..lamda./(4NA.sup.2)=dF/D.sub.b. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D.sub.b=10 mm, and focal spot diameter d=15 .mu.m, the laser beam waist half-length L would be 240 .mu.m.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By

scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 .mu.J. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F.sub.1, F.sub.2, F.sub.3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**. Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device **10** and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorp-

tion band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6.times.6.times.4 mm=144 mm.sup.3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E.sub.1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1.times.1 mm plane will require 66.times.66=4356 pulses. The 2 side walls will require 2.times.66.times.5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E.sub.1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12.degree. C.=49.degree. C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6.degree. C. (T=43.degree. C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1.times.1.times.4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E.sub.1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D.sub.b=10 mm would allow for focusing into a spot of about

4 .mu.m in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm.sup.2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 .mu.J, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm.sup.2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t.sub.pulse<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

The invention claimed is:

1. A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:

a. generating, using a computer, an image of at least a portion of a crystalline lens of the eye based on detecting remitted light from locations distributed throughout a volume of the crystalline lens;

b. processing data including the image data so as to determine a targeted treatment region in the lens of the eye, wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule and does not transect the posterior capsule of the lens;

c. directing a laser beam, under computer guided control, in a first pattern to photodisrupt at least a portion of lens tissue of the eye to create a light scattering region; and

d. subsequently directing the laser beam, under computer guided control, in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region, thereby effecting patterned laser cutting of lens tissue for subsequent removal of pieces or segments of lens tissue.

2. The method of claim 1, wherein the light scattering region comprises an element selected from the group consisting of: a gas bubble, a crack, a tissue fragment, a tissue rupture.

3. The method of claim 1, wherein photo disrupting at least a portion of the posterior tissue structure to create a light scattering region comprises irradiating the portion of the posterior tissue structure with a pattern formed by scanning the laser beam.

4. The method of claim 3, wherein irradiating with a pattern comprises creating a planar pattern at a first depth, and repeatedly irradiating with this pattern at one or more additional depths.

5. The method of claim 4, wherein the one or more additional depths is more anterior than the first depth.

6. The method of claim 3, wherein the pattern is a three-dimensional pattern.

7. The method of claim 3, wherein the pattern is selected from the group consisting of: two or more intersecting straight lines, a crosshatched pattern comprising two or more sets of intersecting lines, one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines.

8. The method of claim 3, wherein one or more cuts are created by the laser beam within a lens capsule of the eye, and wherein the pattern is selected from the group consisting of: a circular pattern, a spiral pattern, and an axially stepping spiral pattern.

9. The method of claim 3, wherein one or more cuts are created by the laser beam within a crystalline lens of the eye, and wherein the pattern is configured such that the one or more cuts facilitate prefragmentation of the lens for later phacoemulsification.

10. The method of claim 3, wherein one or more cuts are created by the laser beam within a crystalline lens of the eye, and wherein the pattern is configured such that the one or more cuts divide the lens into fragments of sufficiently small size so that they may be removed through a lumen of an ophthalmic aspiration probe.

11. The method of claim 1, wherein the targeted tissue structure is a structure selected from the group consisting of: a cornea, an iris, a lens capsule, a crystalline lens, a crystalline lens cortex, crystalline lens nucleus, and an opacity within a crystalline lens.

12. The method of claim 1, wherein the image is acquired using a device selected from the group consisting of: a camera, an optical coherence tomography system, a confocal microscope system, and an ultrasound transducer.

13. The method of claim 1, further comprising phacoemulsifying the one or more structures of the eye.

14. The method of claim 1, further comprising dynamically adjusting a characteristic of the laser beam, the laser beam characteristic selected from the group consisting of: focus, position, power, pulse energy, repetition rate, and scanning speed.

15. The method of claim 1, wherein the light scattering region is located in the posterior part of the targeted region.

16. A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:

a. generating, using a computer, an image of at least a portion of a crystalline lens of the eye based on detecting remitted light from locations distributed throughout a volume of the crystalline lens using an optical coherence tomography imaging system;

b. processing data including image data, using a computer, so as to determine a targeted treatment region of the lens of the eye based at least in part upon the image, the targeted treatment region comprising a posterior cutting boundary located anterior to the posterior capsule of the lens;

c. directing a laser beam in a first pattern, controlled by a computer, to photodisrupt at least a portion of lens tissue anterior to the posterior capsule and posterior to the targeted treatment region in the lens of the eye to create a light scattering region; and

d. subsequently directing the laser beam in a second pattern, controlled by a computer, in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region and effect patterned laser cutting of lens tissue of the target region into one or more pieces or segments for subsequent removal.

17. A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:

a. operating an optical coherence tomography imaging system, controlled by a computer system, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient;

b. processing data including image data, using the computer system, so as to construct a targeted treatment region of the lens of the eye, the targeted treatment region being disposed anterior to the posterior capsule of the lens; and

c. generating a beam of light using a pulsed laser system, wherein the pulsed laser system is guided by the computer system so as to effect fragmentation of lens tissue of the targeted treatment region in a fragmentation pattern within the targeted treatment region, the fragmentation comprising:

i. directing a laser beam in a first pattern to photodisrupt at least a portion of lens tissue of the eye to create a light scattering region; and

ii. subsequently directing the laser beam in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region and effect 3-Dimensional patterned laser cutting of the lens tissue for subsequent removal.

18. The method of claim 17, wherein the pulsed laser system is guided by the computer system based at least in part on the identified targeted treatment region so as to effect a capsulotomy of the anterior lens capsule followed by the fragmentation.

19. A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:

a. operating an imaging system, controlled by a computer system, so as to acquire image data from a crystalline lens of a patient;

b. processing data including the image data, using the computer system, so as to generate a targeted treatment region in the lens of the eye, wherein the targeted treatment region is anterior to the posterior capsule of the lens; and

c. generating a beam of light using a pulsed laser system so as to effect cutting of lens tissue of the targeted treatment region, the cutting comprising:

i. directing a laser beam, under computer-guided control, in a first pattern to photodisrupt at least a portion of lens tissue to create a light scattering region; and

ii. subsequently directing the laser beam, under computer-guided control, in a second pattern in lens tissue anterior to the light scattering region, the second pattern comprising a plurality of intersecting planar incision patterns, so as to effect cutting of lens tissue into a plurality of segments or fragments for subsequent removal.

20. The method of claim **19**, wherein the cutting comprises directing the laser beam in a plurality of 2-dimensional (2-D) planar incision patterns applied at different axial depths in the lens, each 2-D planar incision pattern comprising a plurality of intersecting lines.

21. The method of claim **19**, wherein the cutting comprises directing the laser beam in a plurality of 2-dimensional (2-D) planar incision patterns applied at different axial depths in the lens, each 2-D planar incision pattern comprising a plurality of concentric circular lines.

22. The method of claim **19**, wherein a segmented or fragmented piece comprises a length of at least 1 mm.

23. The method of claim **19**, wherein the pulsed laser system is guided by the computer system so as to effect a capsulotomy of the anterior lens capsule followed by the segmentation or fragmentation of lens material.

* * * * *

EXHIBIT E

US008709001B2

(12) **United States Patent**
Blumenkranz et al.

(10) **Patent No.: US 8,709,001 B2**
(45) **Date of Patent: *Apr. 29, 2014**

(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

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(73) Assignee: **Optimedica Corporation**, Santa Ana, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/588,966**

(22) Filed: **Aug. 17, 2012**

(65) **Prior Publication Data**

US 2013/0023864 A1 Jan. 24, 2013

Related U.S. Application Data

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(51) **Int. Cl.**
A61B 18/20 (2006.01)

(52) **U.S. Cl.**
USPC **606/4**; 606/6

(58) **Field of Classification Search**
USPC 606/3–6, 17; 128/898
See application file for complete search history.

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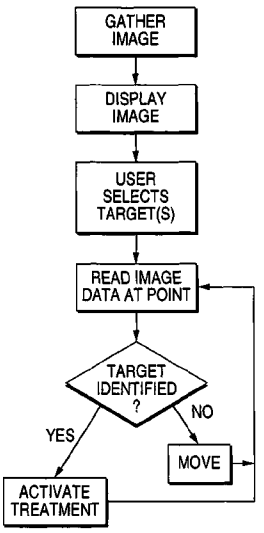
Primary Examiner — Bill Thomson
Assistant Examiner — Jeffrey Lipitz
(74) *Attorney, Agent, or Firm* — Optimedica Corporation

(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye tissue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

24 Claims, 10 Drawing Sheets



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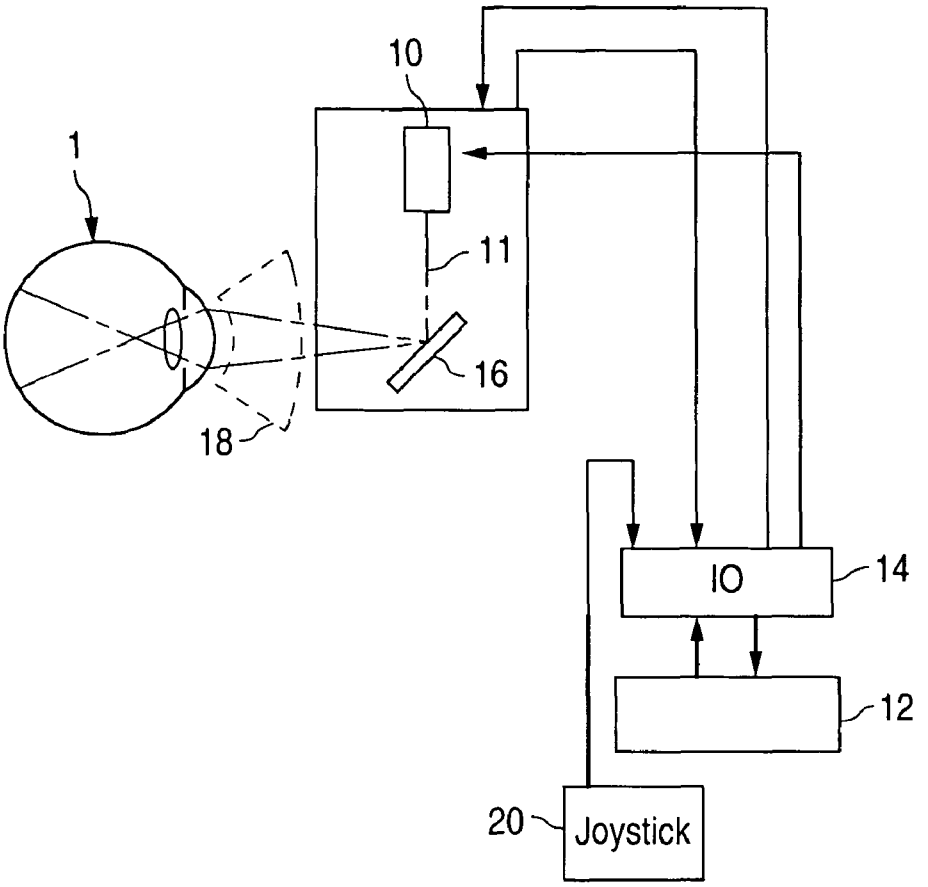


FIG. 1

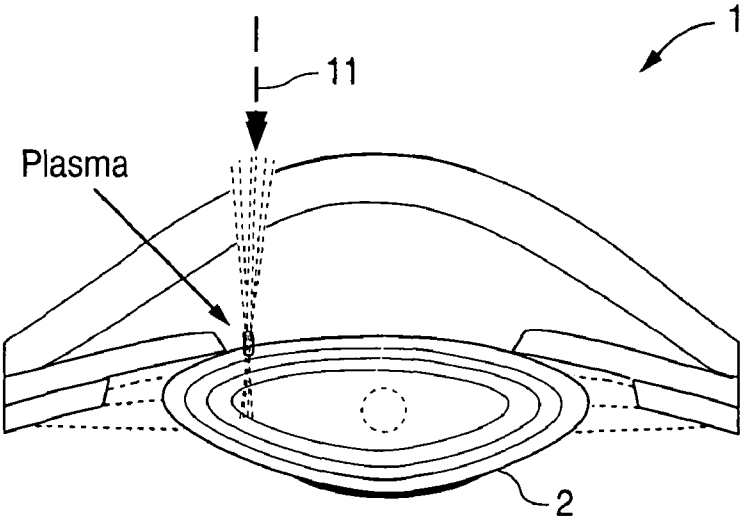
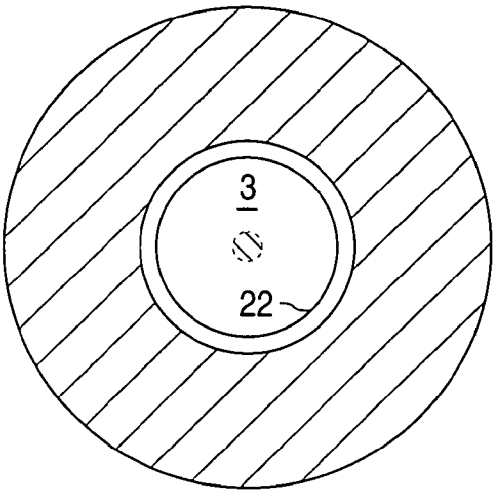


FIG. 2



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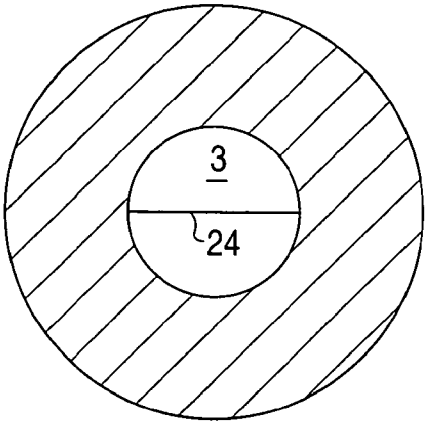

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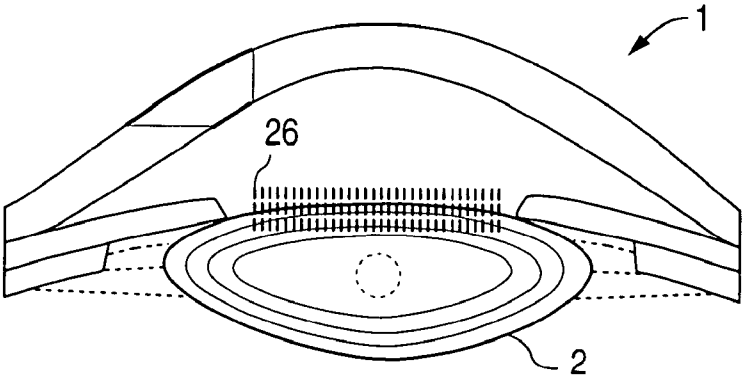

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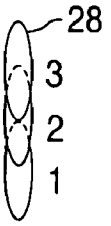

FIG. 6

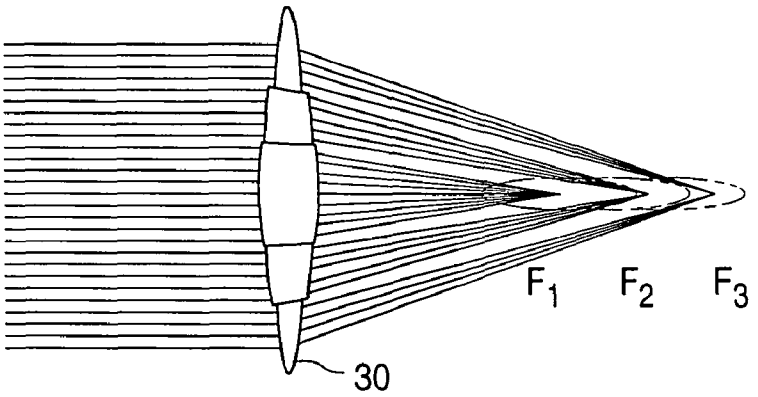

FIG. 7A

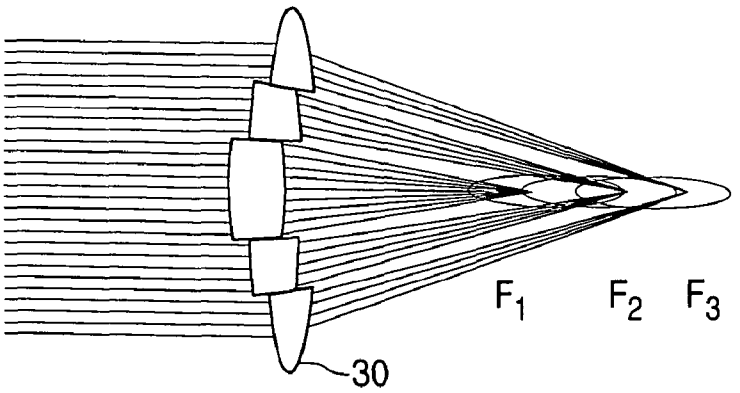

FIG. 7B

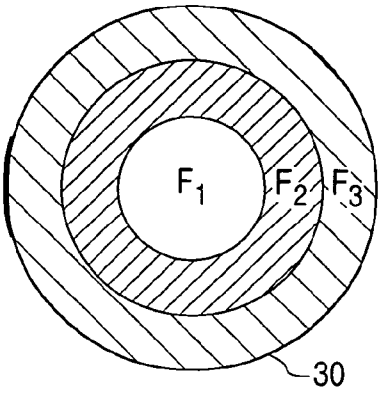

FIG. 7C

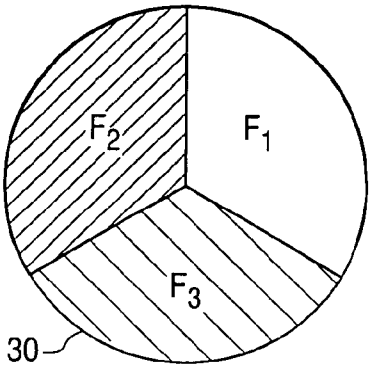

FIG. 7D

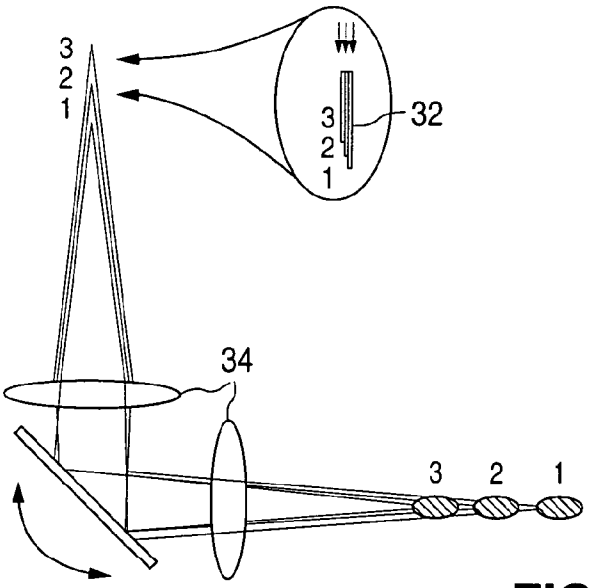

FIG. 8

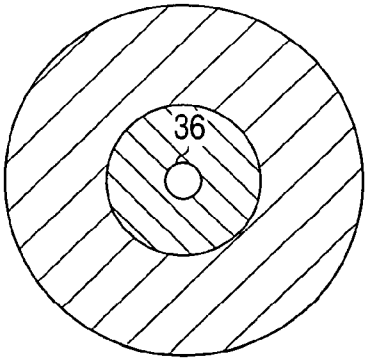

FIG. 9A

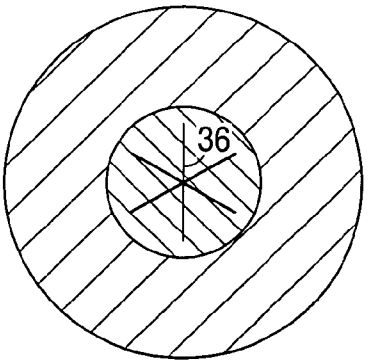

FIG. 9B

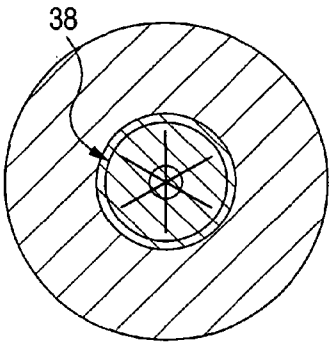

FIG. 10A

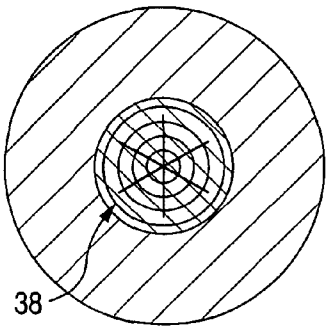

FIG. 10B

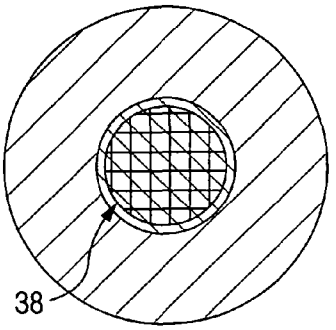

FIG. 10C

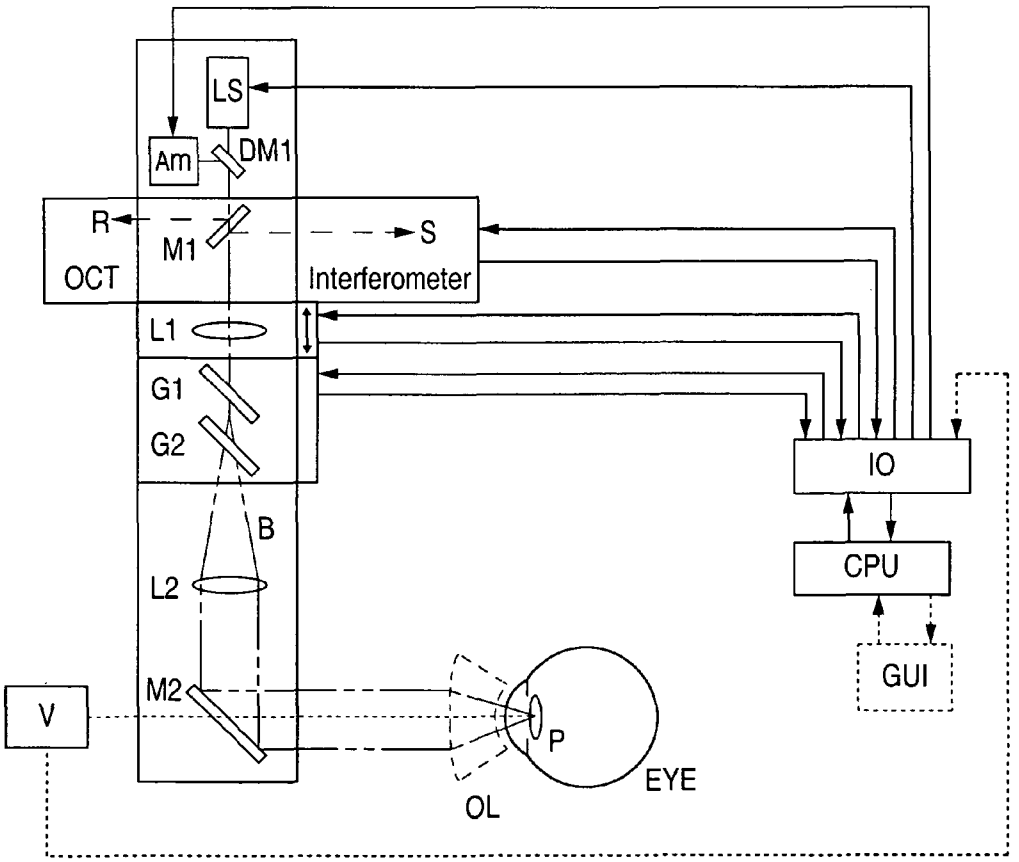

FIG. 11

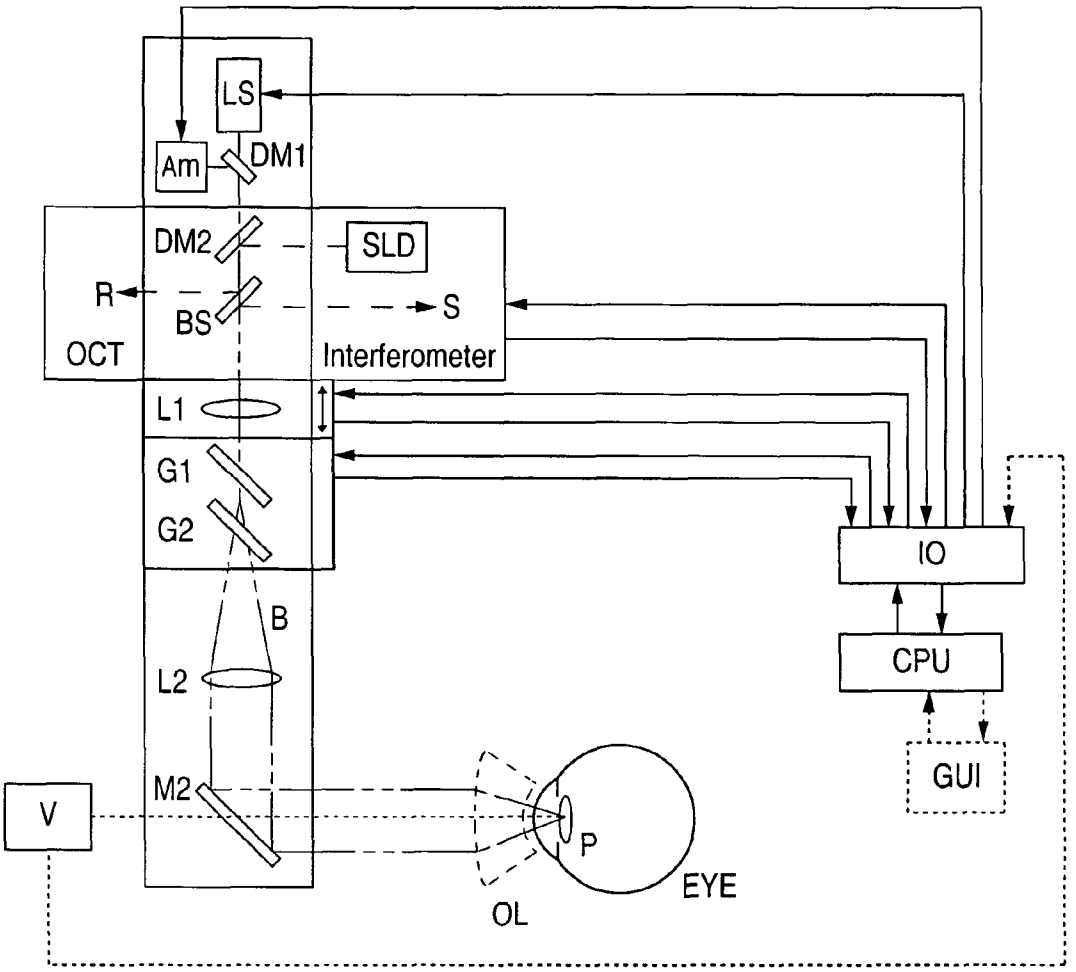
LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

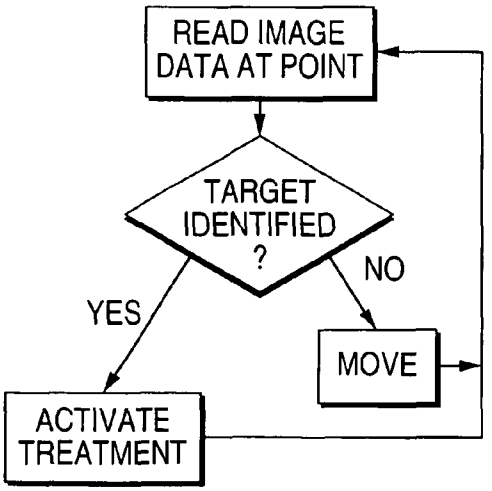
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

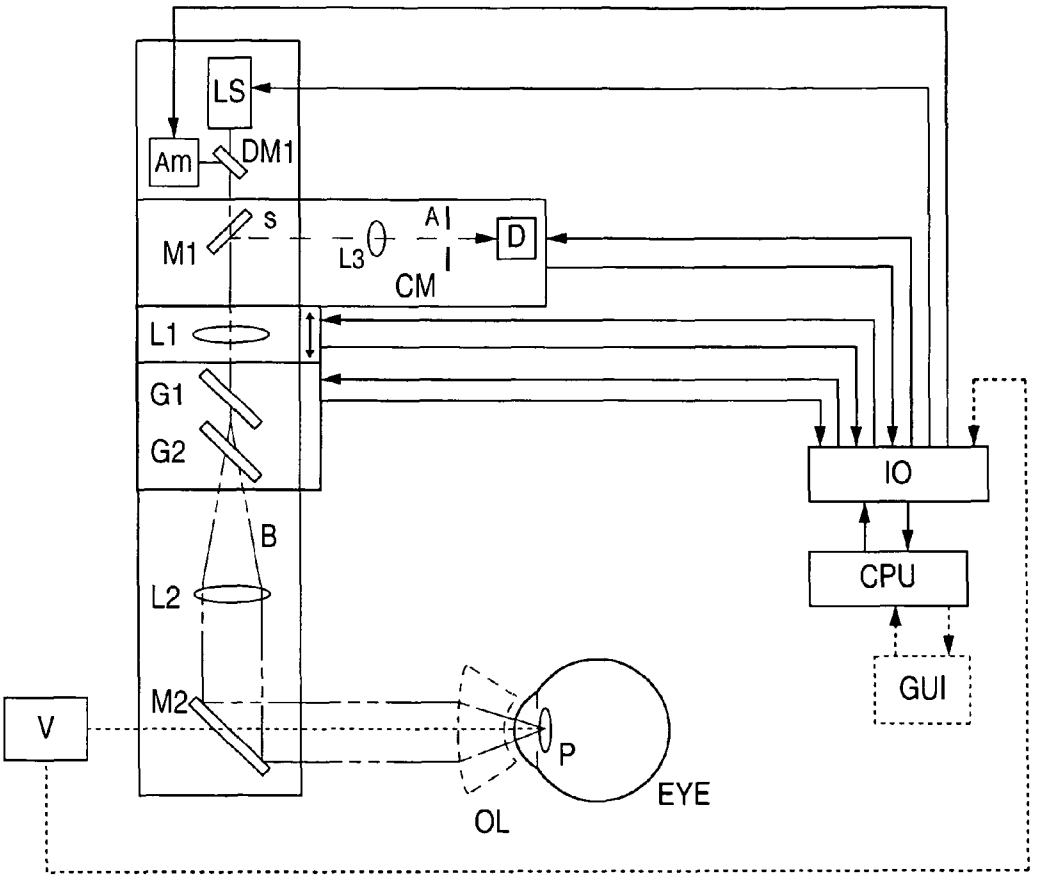

FIG. 13

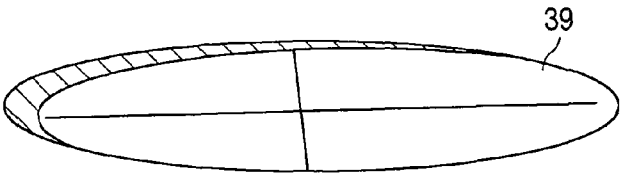

FIG. 16

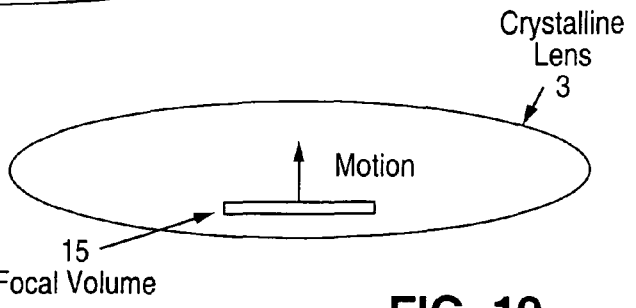

FIG. 19

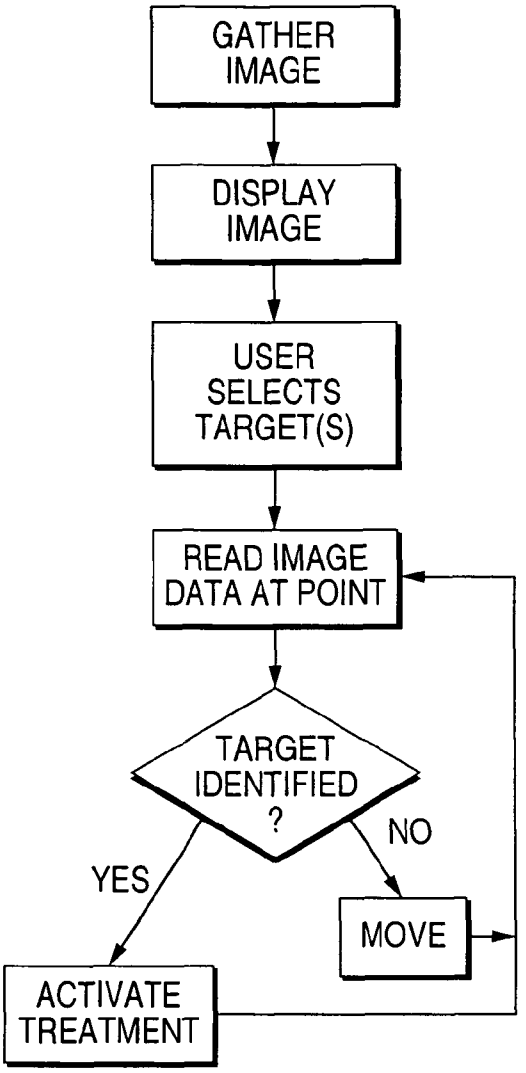
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

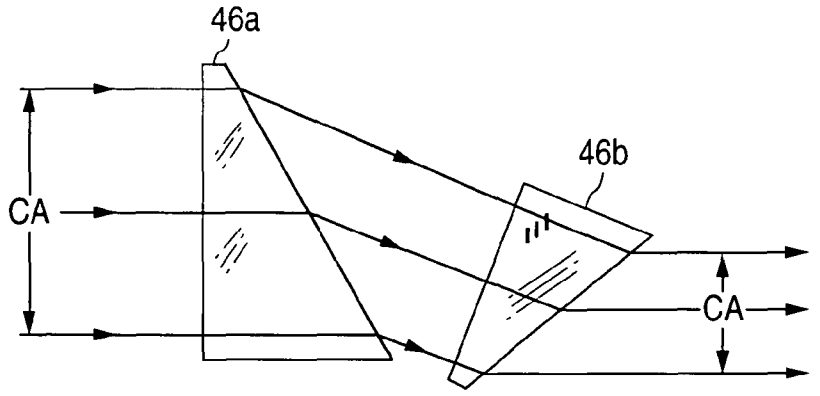
46a
46b
CA
CA

FIG. 18

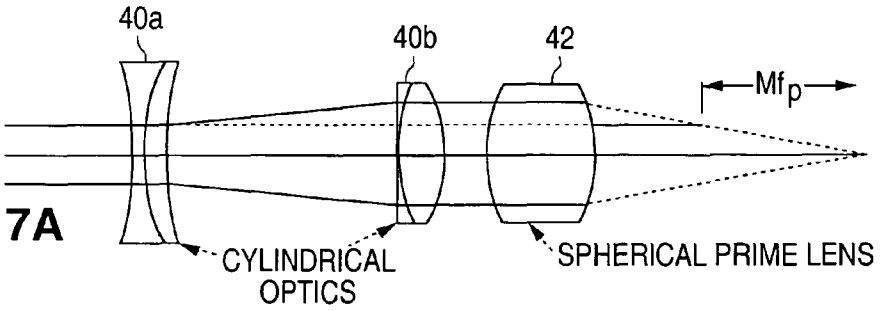

FIG. 17A

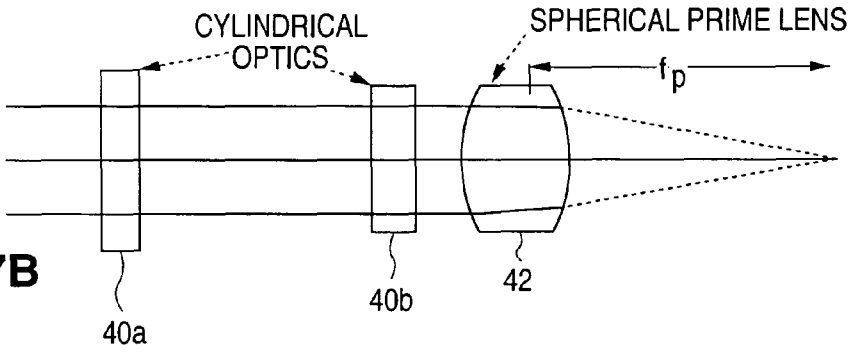

FIG. 17B

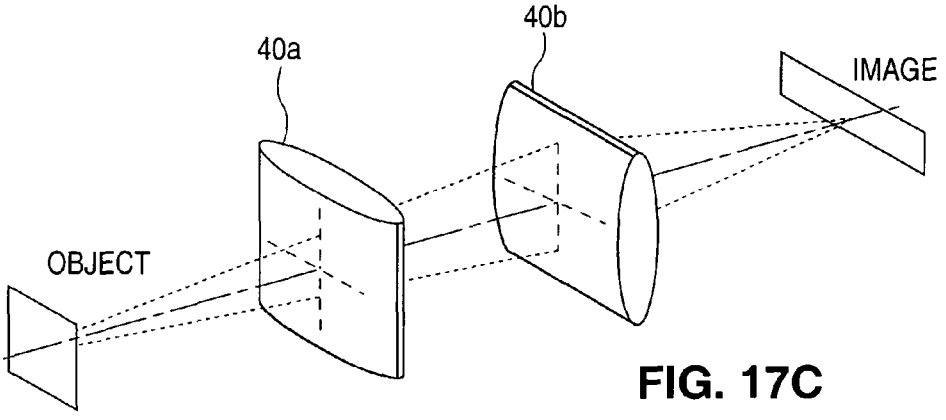

FIG. 17C

FIG. 20

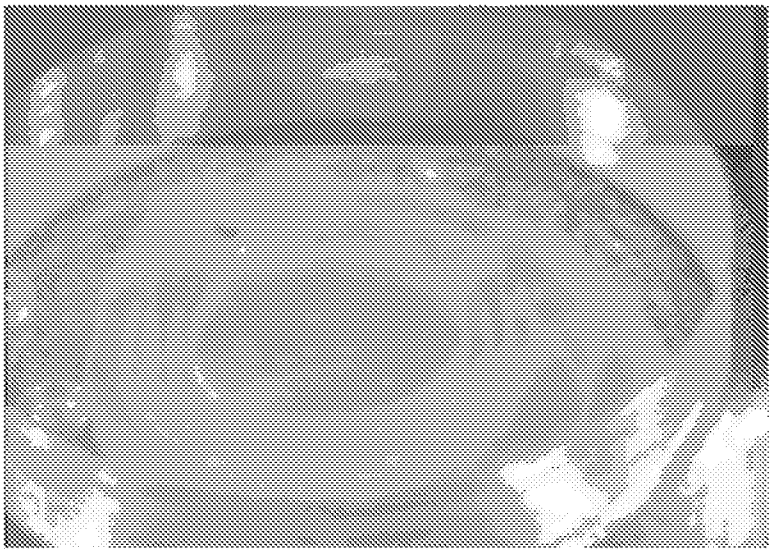

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. In *Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and

Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and

the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**, **2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**, **2**, **3**) focused with a set of lenses into multiple points (**1**, **2**, **3**) and thus producing plasma at different depths inside the tissue (**1**, **2**, **3**).

FIG. **9** is a diagram illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the

tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda(2\cdot NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L\sim\lambda/(4\cdot NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial

length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of

cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device **10** and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and

expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and

tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a*/b and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a*/b to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that

various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method for cataract surgery on an eye of a patient using a pulsed laser surgical system, comprising:

operating an imaging system so as to acquire image data from locations distributed throughout a volume of a cataractous crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens;

constructing, using a computer system, an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and

operating the surgical system to direct a pulsed laser treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens.

2. The method of claim **1**, wherein the imaging system is an optical coherence tomography imaging system.

3. The method of claim **1**, further comprising aligning a treatment beam with a target tissue of the patient prior to creating the capsulotomy.

4. The method of claim **3**, wherein the aligning comprises generating an image of an alignment pattern on a tissue of the patient's eye.

5. The method of claim **4**, wherein the aligning comprises adjusting the size, location or shape of the alignment pattern based on user input.

6. The method of claim **1**, wherein the posterior boundary does not transect the posterior capsule of the lens.

7. The method of claim **1**, further comprising identifying, using a computer system, a lens fragmentation region comprising a posterior boundary that does not transect the posterior capsule of the lens.

8. The method of claim **7**, wherein the lens fragmentation region comprises a constructed anterior boundary and said posterior boundary of the lens fragmentation region.

9. The method of claim **7**, further comprising operating the surgical system so as to direct a treatment beam in a second pattern based on the fragmentation region so as to fragment the crystalline lens.

10. The method of claim **1**, wherein all laser cutting occurs anterior to the posterior capsule surface.

11. The method of claim **1**, entering user input to an interface so as to identify one or more parameters of the cataract surgery procedure.

12. The method of claim **1**, wherein the pulsed laser surgical system comprises:

a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure;

the imaging system configured for imaging tissue of a cataractous crystalline lens of the patient using non-visible light;

an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens; and

a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system.

13. A method for cataract surgery on an eye of a patient using a pulsed laser surgical system, comprising:

operating an optical coherence tomography (OCT) imaging system so as to acquire OCT image data from locations distributed throughout a volume of a crystalline lens of the patient;

processing the image data using a computer system so as to identify and locate within the patient's lens an anterior capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and

operating the surgical system to direct a treatment laser beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens, wherein positioning of the treatment beam focal zone in the lens during the patterned cutting is guided by the computer system based on the constructed cutting region.

14. The method of claim **13**, further comprising performing an alignment step, prior to creating the anterior capsulotomy, so as to align a treatment beam with a target tissue of the patient.

15. The method of claim **13**, further comprising constructing, using a computer, one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens.

16. The method of claim **13**, further comprising identifying a lens fragmentation region comprising a posterior boundary that does not transect the posterior capsule of the lens; and operating the surgical system so as to direct a treatment beam in a second pattern based on the fragmentation region so as to fragment the crystalline lens.

17. The method of claim **16**, further comprising identifying, using a computer, a posterior axial cutting limit for positioning of any treatment beam focal zone, such that the posterior axial cutting limit is located anterior to the posterior capsule surface.

18. The system of claim **13**, further comprising receiving input from a user input system that at least partially defines one or more cutting regions.

19. The method of claim **13**, wherein the constructing and locating the anterior capsulotomy cutting region further comprises receiving and processing user input.

20. A method for cataract surgery on an eye of a patient using a pulsed laser surgical system, comprising:

scanning the patient's eye tissues with an imaging system so as to acquire image data of at least a portion of a crystalline lens of the patient and construct an image of at least a portion of the crystalline lens;

constructing, using a computer system, an anterior capsulotomy cutting region based on the image data comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule;

constructing, using the computer system, a lens fragmentation region comprising a posterior boundary that does not transect the posterior capsule of the lens;

operating the surgical system to (a) direct a treatment laser beam in a first pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens; and (b) direct a treatment laser beam in a second pattern based on the fragmentation region so as to fragment the crystalline lens into a plurality of

discrete patterned pieces for subsequent removal, wherein the positioning of the treatment laser beam in the first and second patterns is guided by the computer system.

21. The method of claim **20**, further comprising identifying, using a computer, a posterior axial cutting limit for positioning of any treatment beam focal zone, such that the posterior axial cutting limit is located anterior to the posterior capsule surface.

22. The method of claim **20**, wherein the imaging system is an optical coherence tomography imaging system.

23. A method for surgery on an eye of a patient using a pulsed laser surgical system, comprising:

operating an imaging system so as to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient;

processing the image data using a computer system so as to construct cutting region data identifying (a) an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule, and (b) a location of the cutting region within the patient's lens;

determining parameters of a cutting pattern based on the image data and/or cutting region data; and

operating the surgical system to direct a focal zone of a laser treatment beam within the lens, wherein positioning of the treatment beam focal zone within the lens is guided by the computer system based on the cutting pattern so as to incise an anterior capsulotomy in the crystalline lens.

24. The method of claim **23**, wherein the imaging system employs an optical coherence tomography imaging modality.

* * * * *

EXHIBIT F

US009095415B2

(12) **United States Patent**
Blumenkranz et al.

(10) **Patent No.: US 9,095,415 B2**
(45) **Date of Patent: *Aug. 4, 2015**

(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

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(58) **Field of Classification Search**

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See application file for complete search history.

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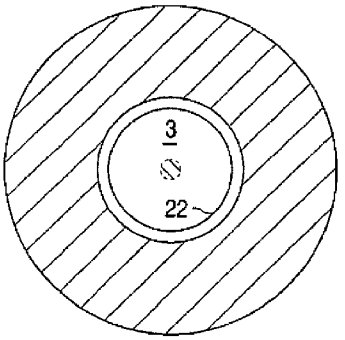
(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye issue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

24 Claims, 10 Drawing Sheets



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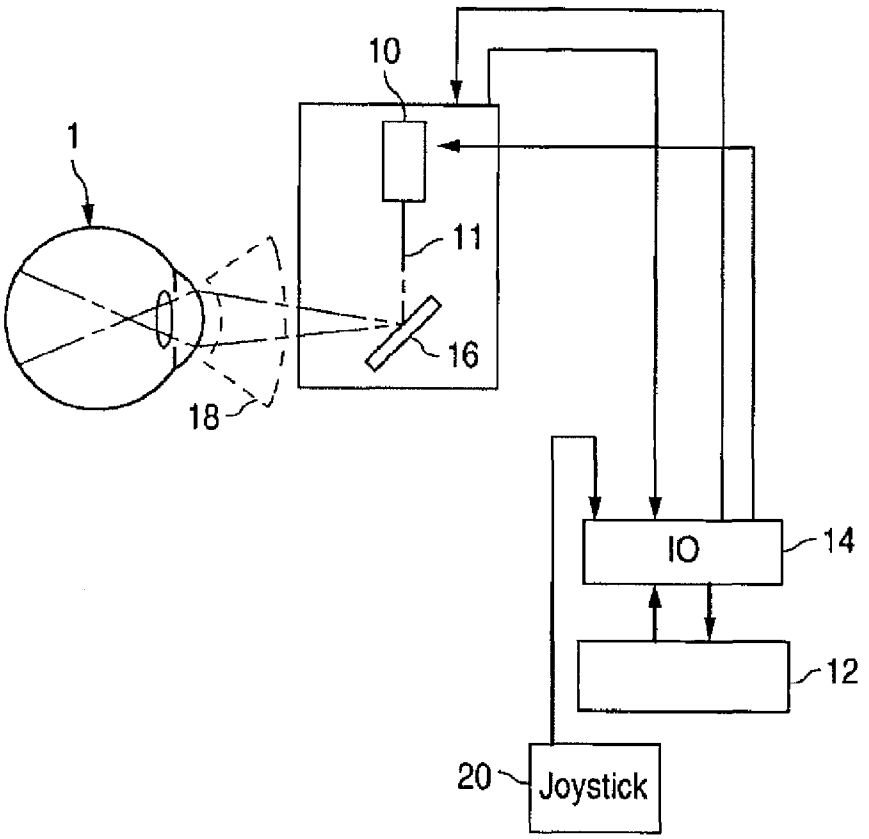

FIG. 1

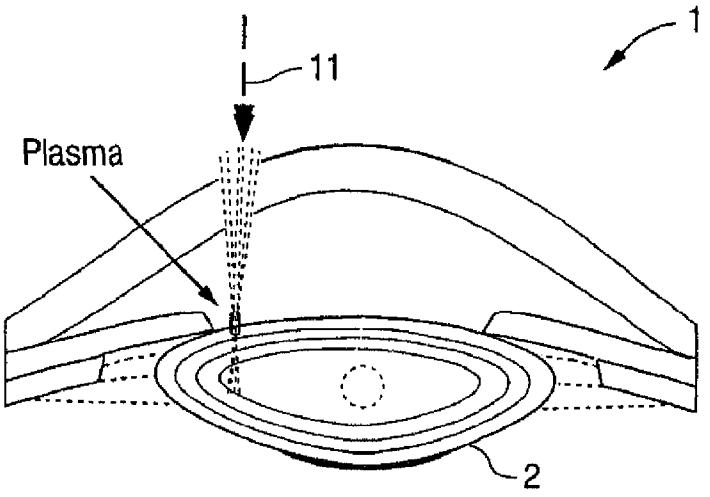

FIG. 2

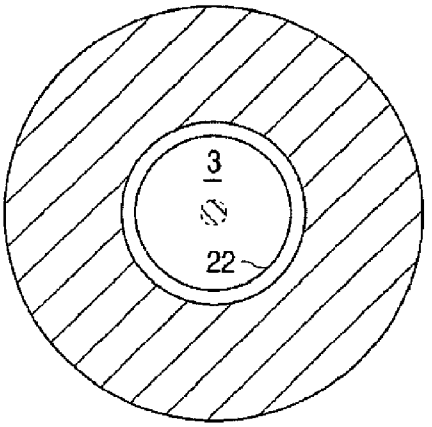

FIG. 3

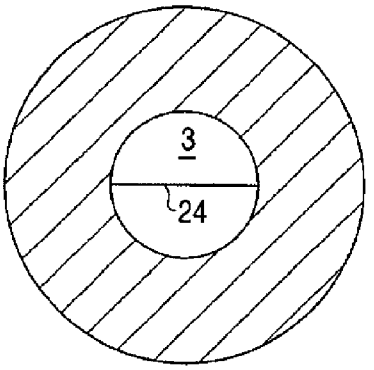

FIG. 4

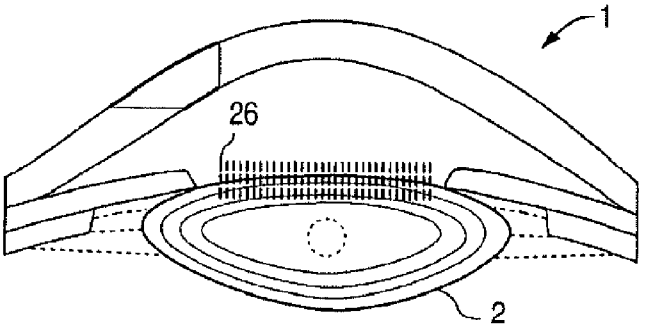

FIG. 5

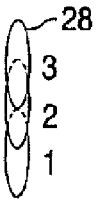

FIG. 6

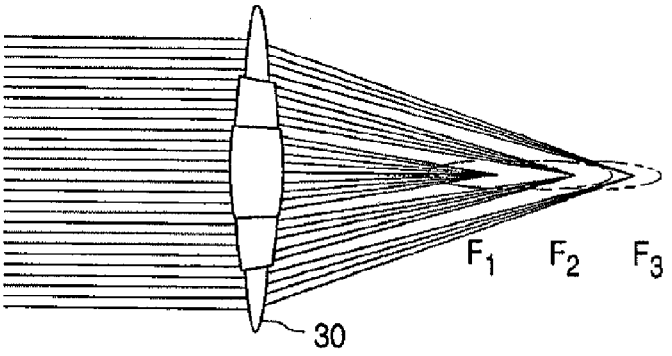

FIG. 7A

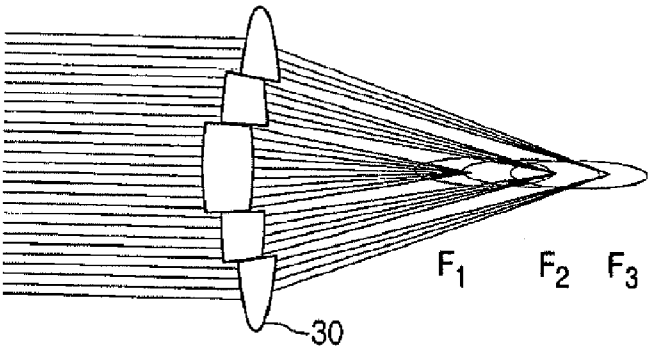

FIG. 7B

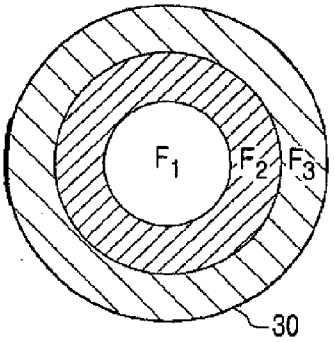

FIG. 7C

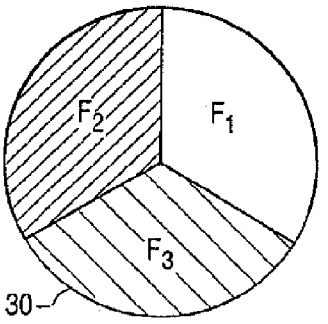

FIG. 7D

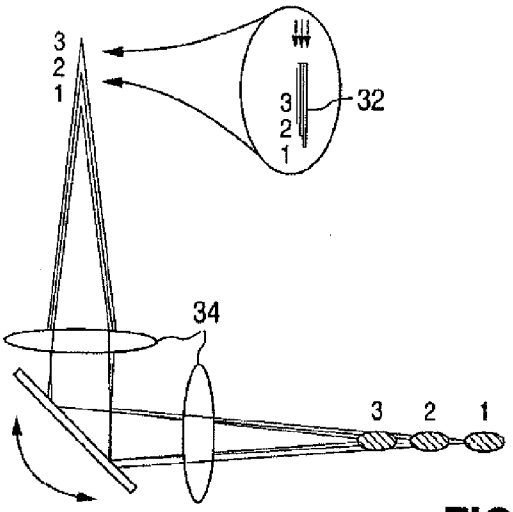

FIG. 8

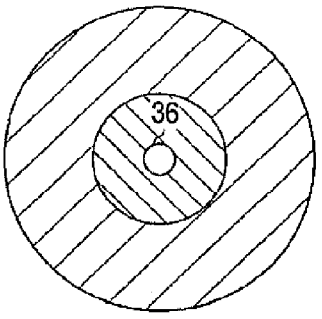

FIG. 9A

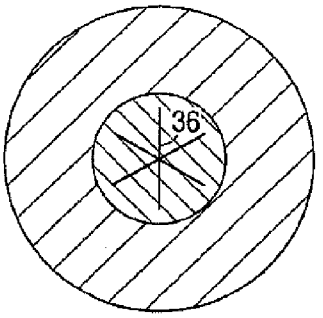

FIG. 9B

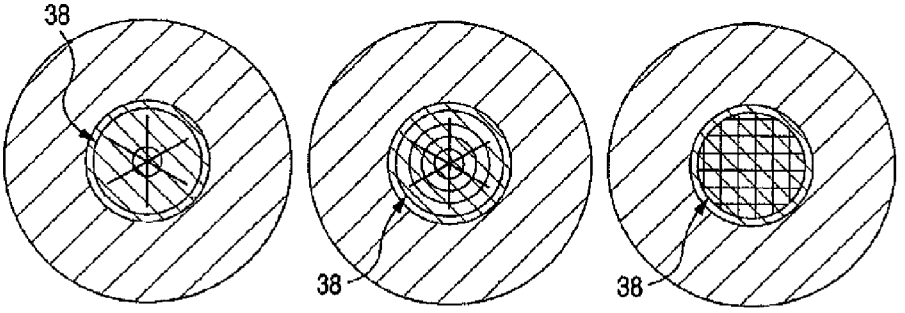

FIG. 10A FIG. 10B FIG. 10C

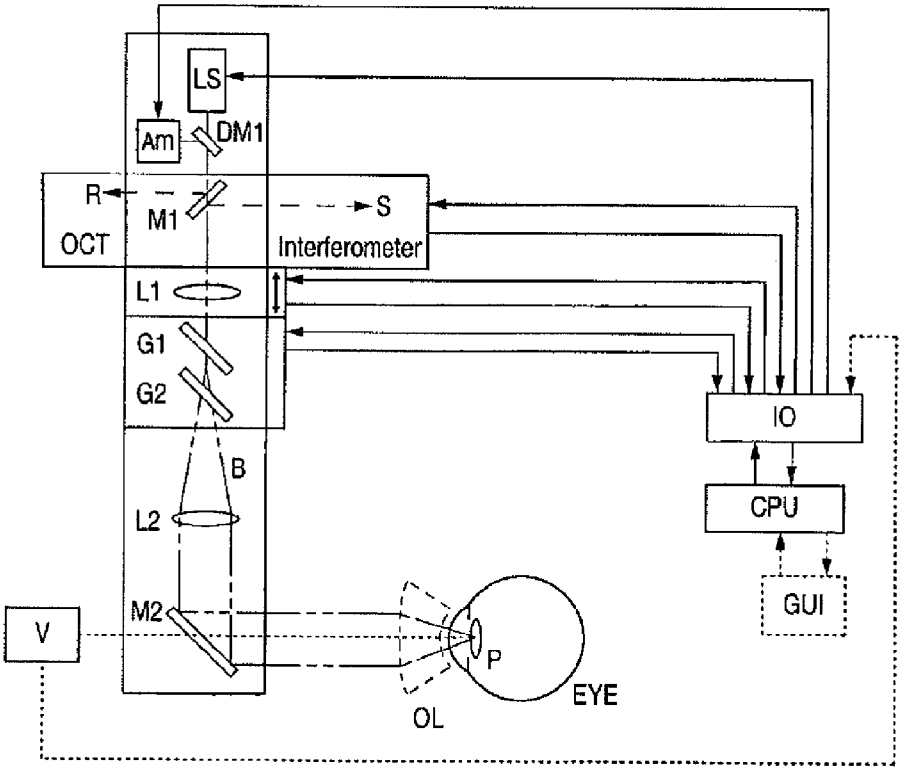

FIG. 11

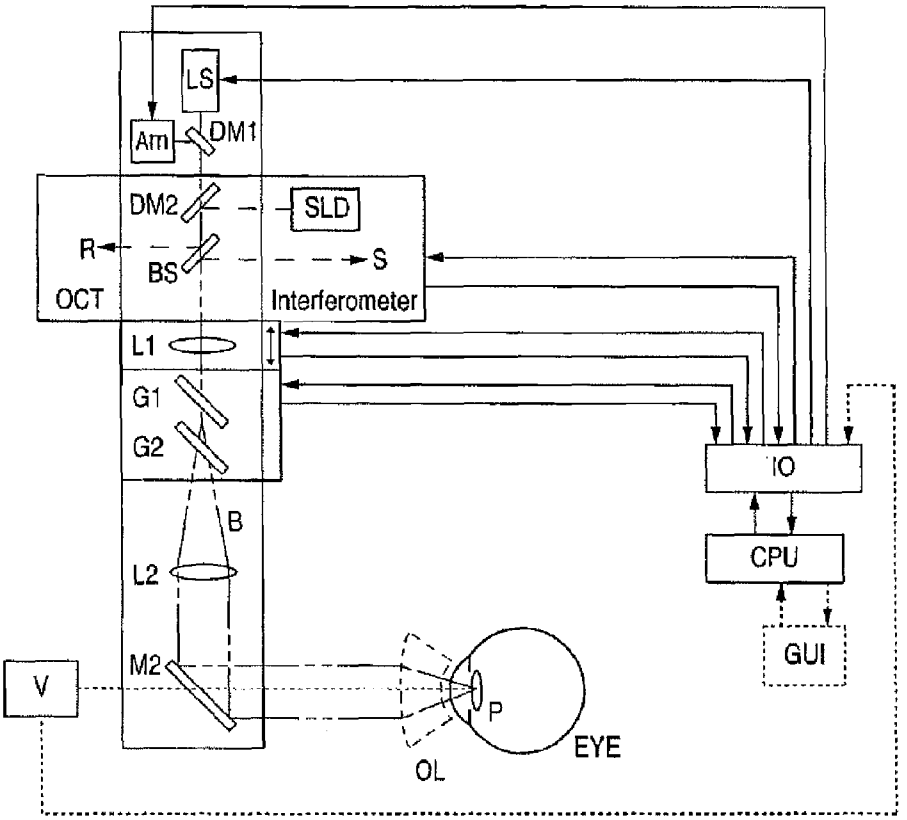
LS
Atm
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

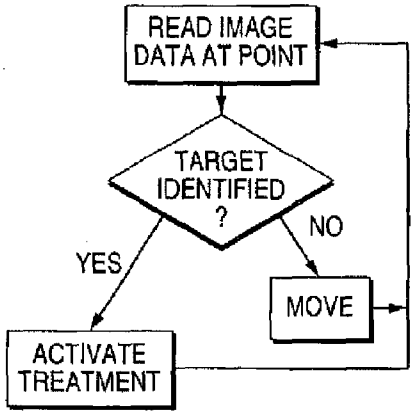
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

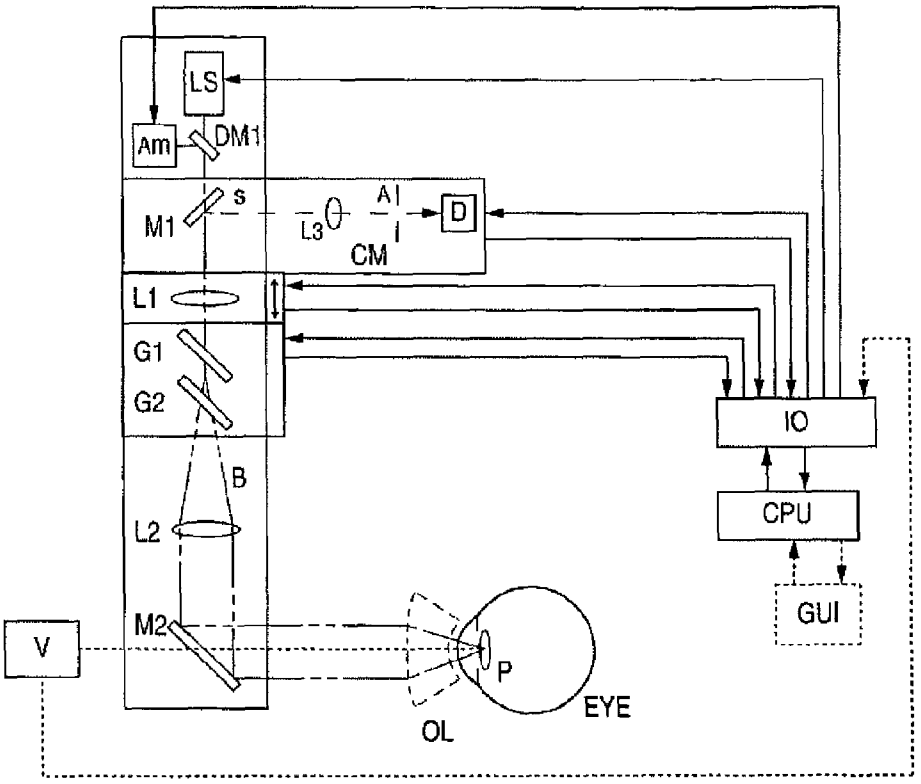

FIG. 13

FIG. 16

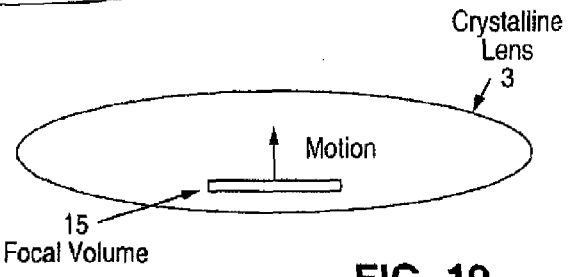

FIG. 19

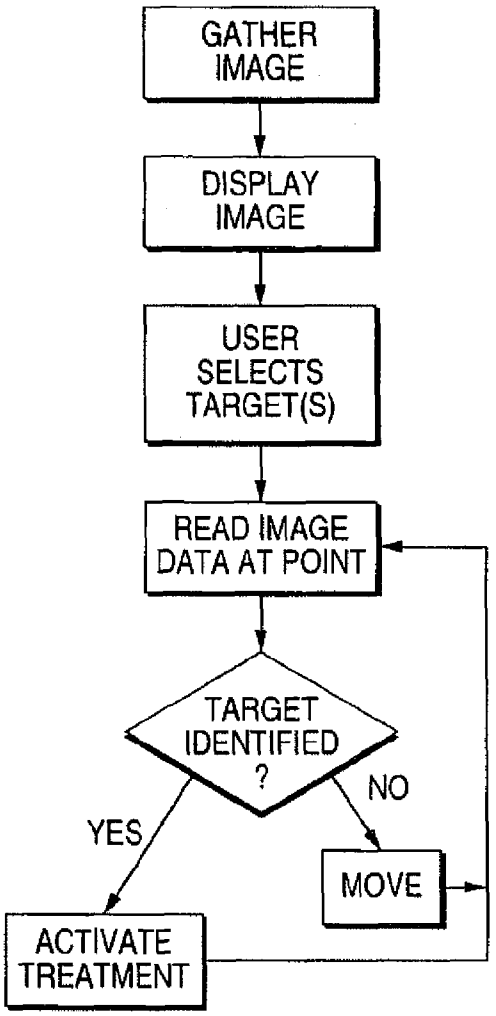
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

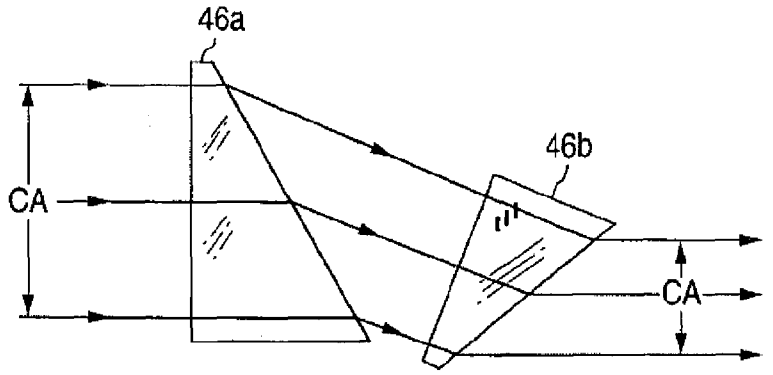
46a
46b
CA
CA

FIG. 18

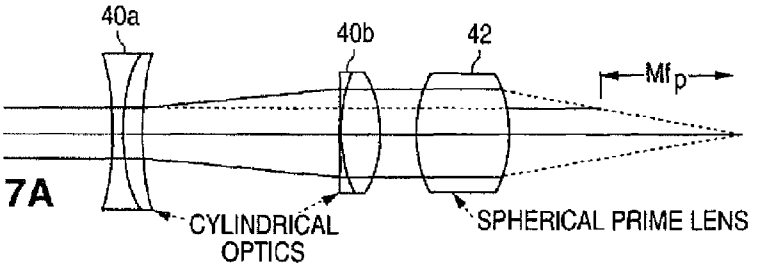

FIG. 17A

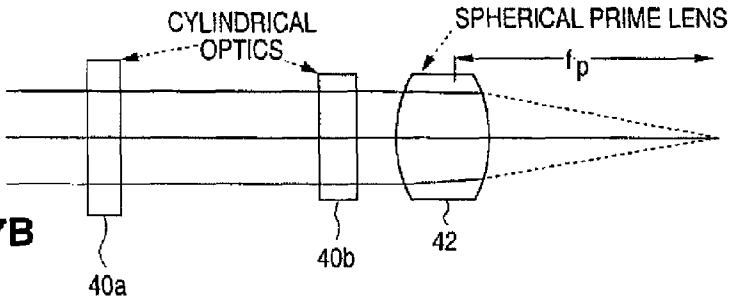

FIG. 17B

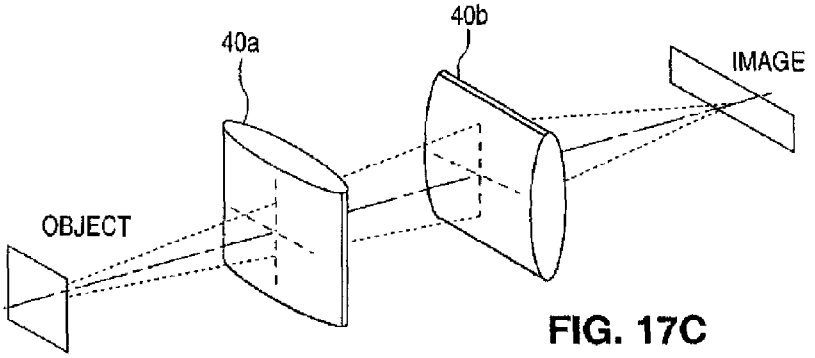

FIG. 17C

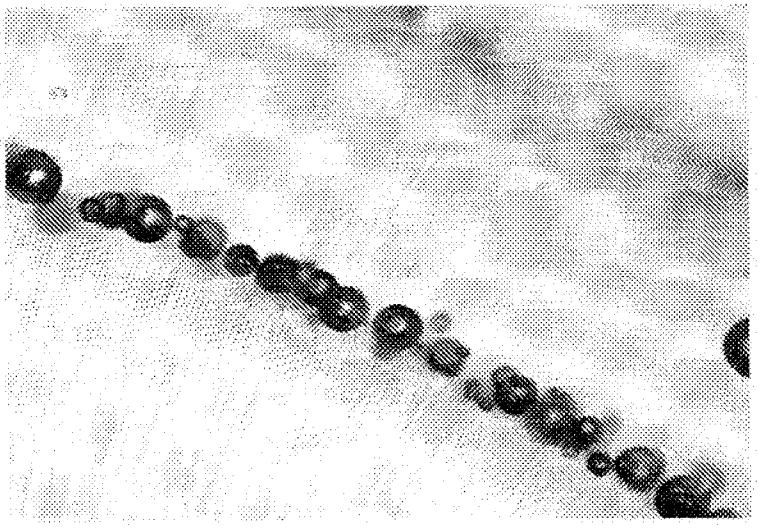

FIG. 20

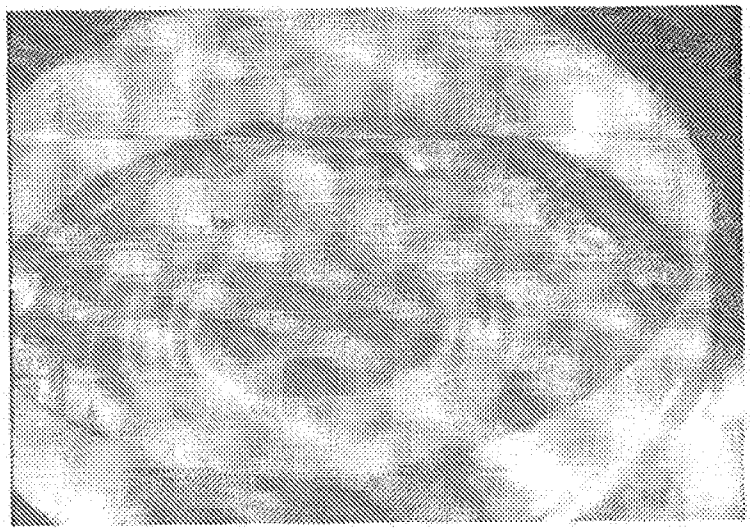

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 13/588,966, filed Aug. 17, 2012, which is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of all of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9:1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lefts capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading expert's in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis, *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina

by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management,* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior fens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter, Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004; pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is

illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special

circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second local point located at a second depth In the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic, foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto

the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**,**2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**78** are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**,**2**,**3**) focused with a set of lenses into multiple points (**1**,**2**,**3**) and thus producing plasma at different depths inside the tissue (**1**,**2**,**3**).

FIG. **9**A and FIG. **9**B are diagrams illustrating examples of the patterns that can be applied for nucleus segmentation.

FIGS. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**. via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps. alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the

tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and λ is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b =10 mm, and wavelength λ=1.04 μm, the focal spot diameter will be $d\approx\lambda/(2.NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 j/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a local distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam. Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L\sim\lambda/(4.NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial

length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of

cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror), in this configuration, laser source LS may be used, for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which, serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric minors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the x-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device IO and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc. as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (h) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and

expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the stops utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: if a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it wail require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 μJ pulses fragmenting a volume of 15 μm in diameter and 200 μm in length per pulse, then pulses will be applied each 15 μm. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal, temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and

tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these piece's can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a local zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus stream lining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planning it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on die target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that

various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method for incising ocular tissue during a cataract surgical procedure, the method comprising:

operating an imaging device to acquire image data of ocular tissue, the image data including lens interior image data for an interior portion of the lens of a patient's eye;

processing the image data via a control system so as to generate an anterior capsulotomy scanning pattern for scanning a focal zone of a laser beam for performing an anterior capsulotomy, the imaging device being operatively coupled to the control system;

generating the laser beam; and

scanning the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is controlled by the control system based on the image data.

2. The method of claim **1**, wherein the laser beam has a wavelength between 800 nm and 1,100 nm, the laser beam comprises pulses having pulse energy between 1.0 micro joules and 1,000 micro joules, the laser beam comprises pulses having a pulse duration between about 100 femtoseconds and about 10 picoseconds, and the laser beam comprises pulses having a repetition rate between 1 kHz and about 200 kHz.

3. The method of claim **1**, wherein scanning the focal zone of the laser in the anterior capsulotomy scanning pattern includes sequentially applying laser pulses to different depths, wherein the laser pulses are first applied at a maximum depth and then applied to sequentially shallower depths.

4. The method of claim **1**, further comprising scanning the focal zone of the laser beam to segment the lens into discrete fragments.

5. The method of claim **4**, wherein the discrete fragments are sized to be removable through a lumen of an ophthalmic aspiration probe.

6. The method of claim **4**, wherein scanning the focal zone of the laser beam to segment the lens into discrete fragments comprises scanning the focal zone in one or more lens fragmentation scanning patterns.

7. The method of claim **6**, wherein the one or more lens fragmentation scanning patterns include at least one of a linear pattern, a planar pattern, a radial pattern, a circular pattern, a spiral pattern, a curvilinear pattern, or two or more overlapping line segments.

8. The method of claim **6**, wherein:

scanning the focal zone in the one or more lens fragmentation scanning patterns comprises sequentially applying laser pulses to different depths within the lens; and

the laser pulses are first applied at a maximum depth within the lens and then applied to sequentially shallower depths within the lens.

9. The method of claim **1**, comprising:

operating a z-axis scanning device to adjust the location of the focal zone of the laser beam parallel to the direction of propagation of the laser beam; and

operating a transverse scanning device to adjust the location of the focal zone transverse to the direction of propagation of the laser beam.

10. The method of claim **9**, wherein the laser beam is acted upon by the z-axis scanning device before being acted upon by the transverse scanning device.

11. The method of claim **10**, wherein:

the z-axis scanning device comprises one or more movable lenses; and

the transverse scanning device comprises one or more controllable scanning elements.

12. The method of claim **1**, further comprising processing the image data via the control system to determine one or more axial locations of the anterior capsule of the lens, and wherein the control system generates the anterior capsulotomy scanning pattern based on the one or more anterior capsule axial locations.

13. The method of claim **12**, further comprising determining, via the control system, a posterior cutting boundary for the anterior capsulotomy scanning pattern based on the one or more anterior capsule axial locations.

14. The method of claim **13**, further comprising determining, via the control system, an anterior cutting boundary for the anterior capsulotomy scanning pattern based on the one or more anterior capsule axial locations.

15. The method of claim **1**, wherein the control system configures the anterior capsulotomy scanning pattern based in part on an input from a user interface.

16. The method of claim **1**, wherein control system controls one or more parameters of the laser beam based on an input from a user interface.

17. The method of claim **16**, wherein the one or more laser beam parameters are selected from the group consisting of pulse energy, pulse repetition rate, pulse duration, and wavelength.

18. A cataract surgical procedure comprising:

operating an imaging device to acquire image data of ocular tissue, the image data including lens interior image data for an interior portion of the lens of a patient's eye;

processing the image data via a control system so as to generate an anterior capsulotomy scanning pattern for scanning a focal zone of a laser beam for performing an anterior capsulotomy, the imaging device being operatively coupled to the control system;

generating the laser beam; and

scanning the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is controlled by the control system based on the image data, and

ultrasonically breaking the lens into pieces.

19. The method of claim **18**, further comprising scanning the focal zone of the laser beam to segment the lens into discrete fragments prior to ultrasonically breaking the lens into pieces.

20. The method of claim **19**, wherein the discrete fragments are sized to be removable through a lumen of an ophthalmic aspiration probe.

21. The method of claim **19**, wherein scanning the focal zone of the laser beam to segment the lens into discrete fragments comprises scanning the focal zone in one or more lens fragmentation scanning patterns.

22. The method of claim **19**, wherein the one or more lens fragmentation scanning patterns include at least one of a linear pattern, a planar pattern, a radial pattern, a circular pattern, a spiral pattern, a curvilinear pattern, or two or more overlapping line segments.

23. The method of claim **18**, further comprising removing the pieces from the lens capsule.

24. The method of claim **23**, further comprising inserting into the lens capsule at least one of an intraocular lens and an optically transparent gel.

* * * * *

EXHIBIT G

US009101448B2

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Blumenkranz et al.

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(45) **Date of Patent: *Aug. 11, 2015**

(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

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This patent is subject to a terminal disclaimer.

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See application file for complete search history.

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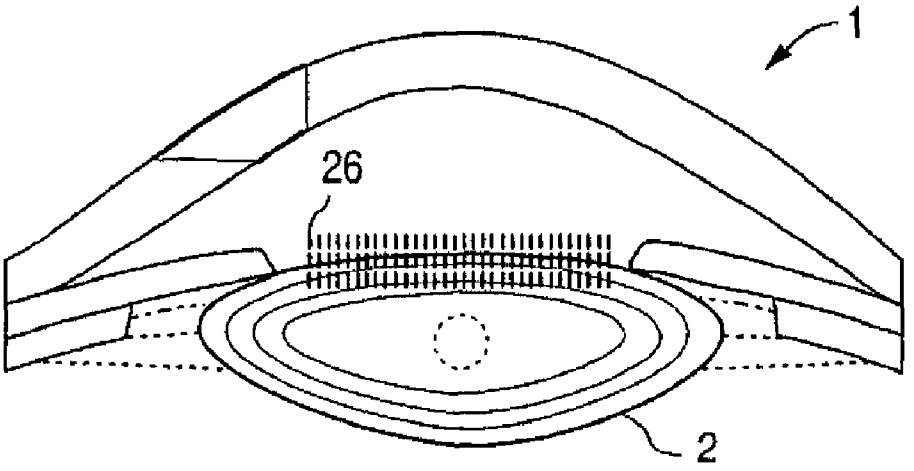
(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye tissue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

20 Claims, 10 Drawing Sheets



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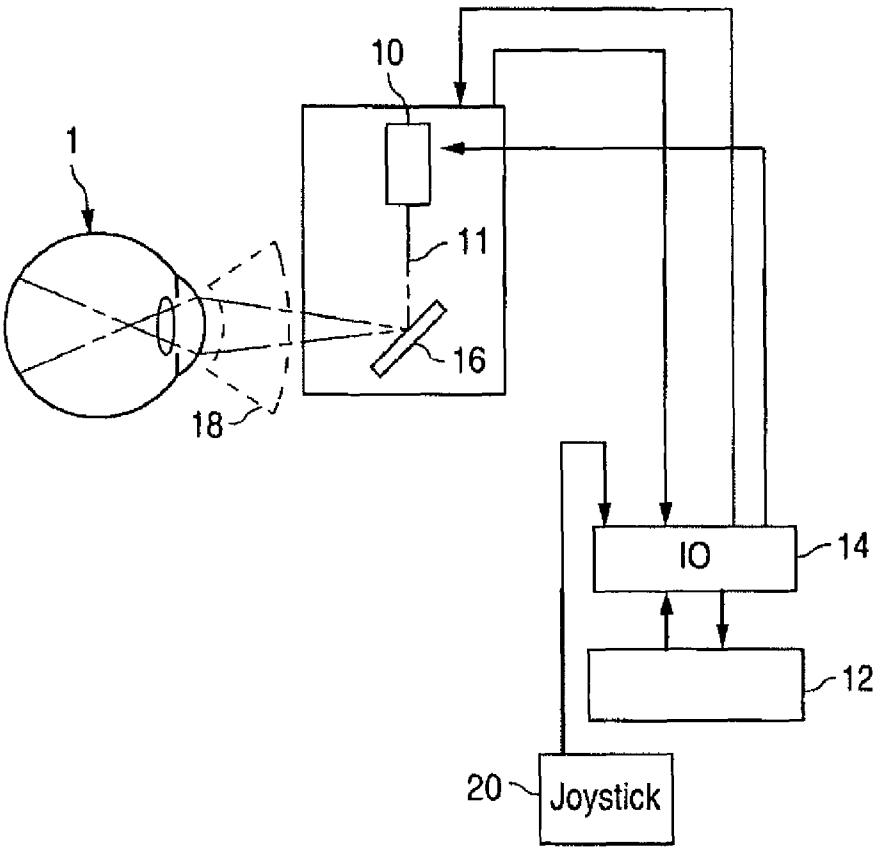


FIG. 1

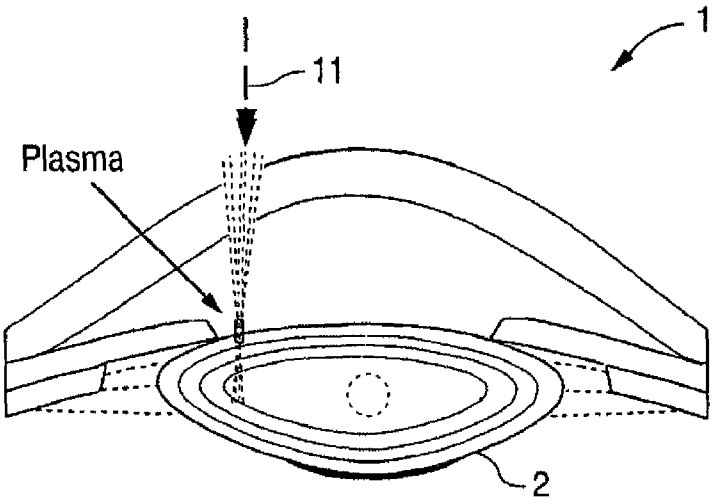


FIG. 2

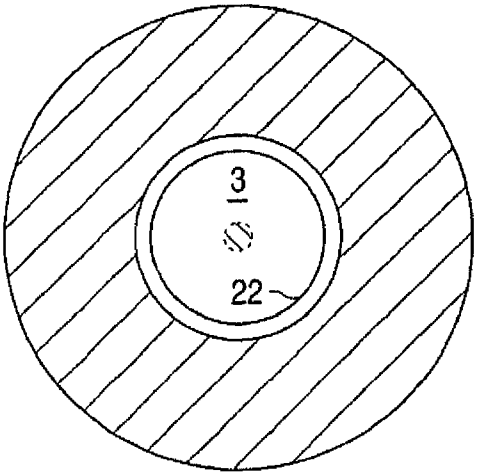


FIG. 3

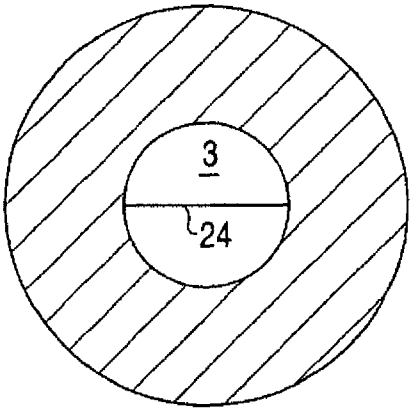


FIG. 4

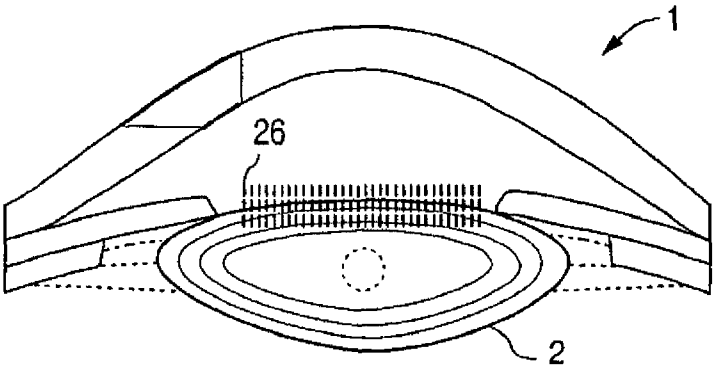


FIG. 5

FIG. 6

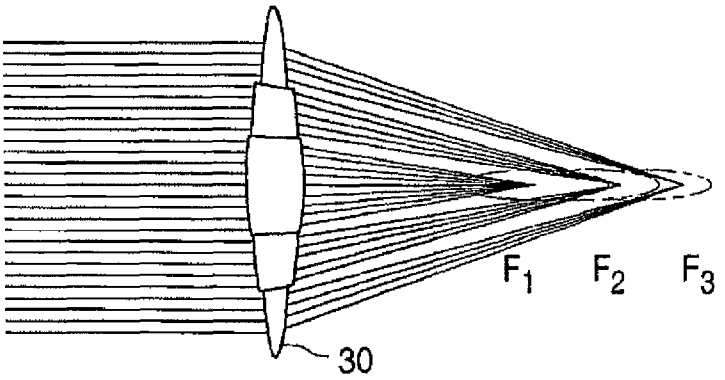


FIG. 7A

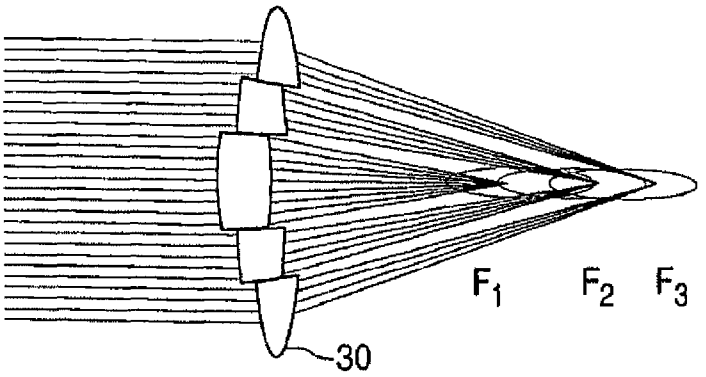


FIG. 7B

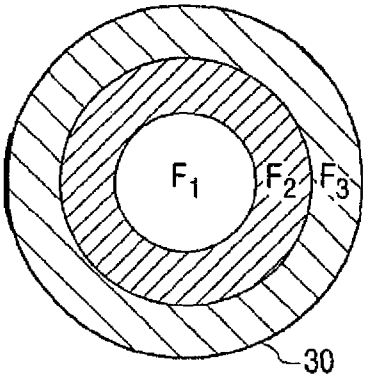


FIG. 7C

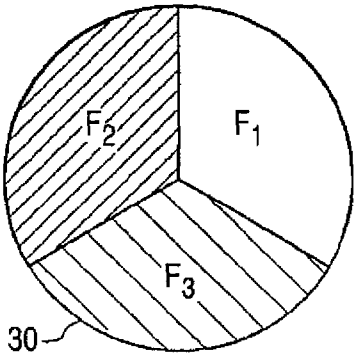


FIG. 7D

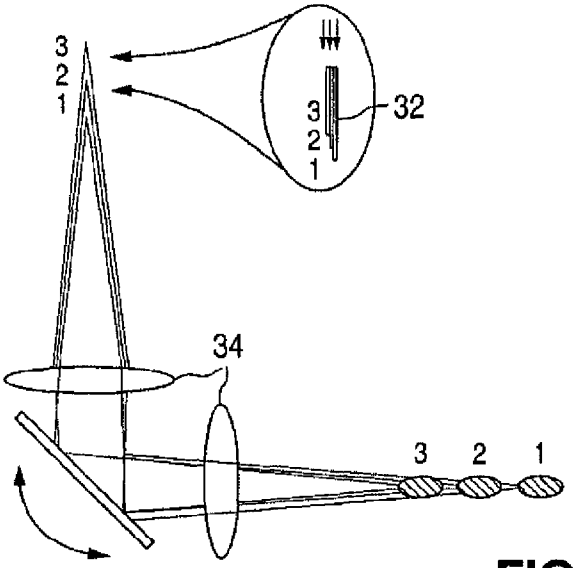


FIG. 8

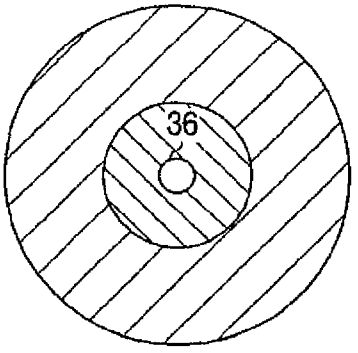


FIG. 9A

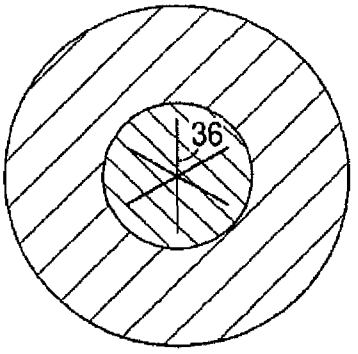


FIG. 9B

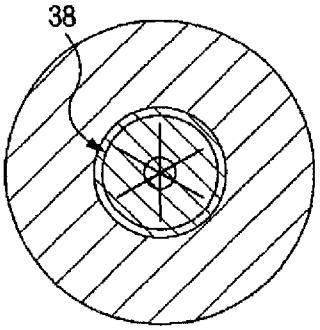


FIG. 10A

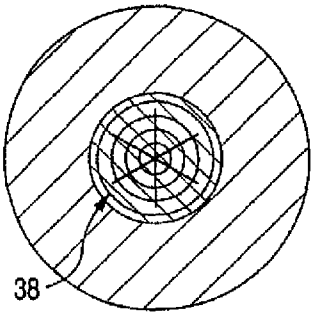


FIG. 10B

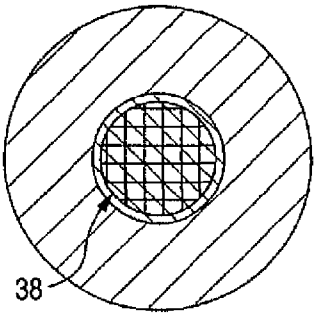


FIG. 10C

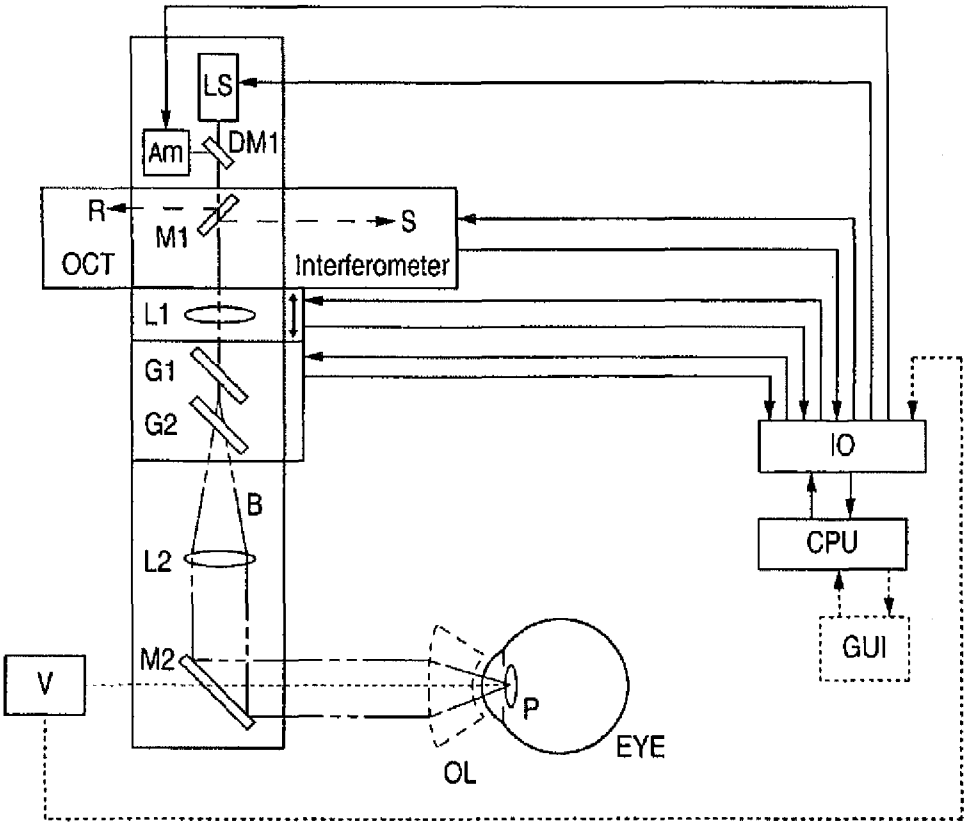
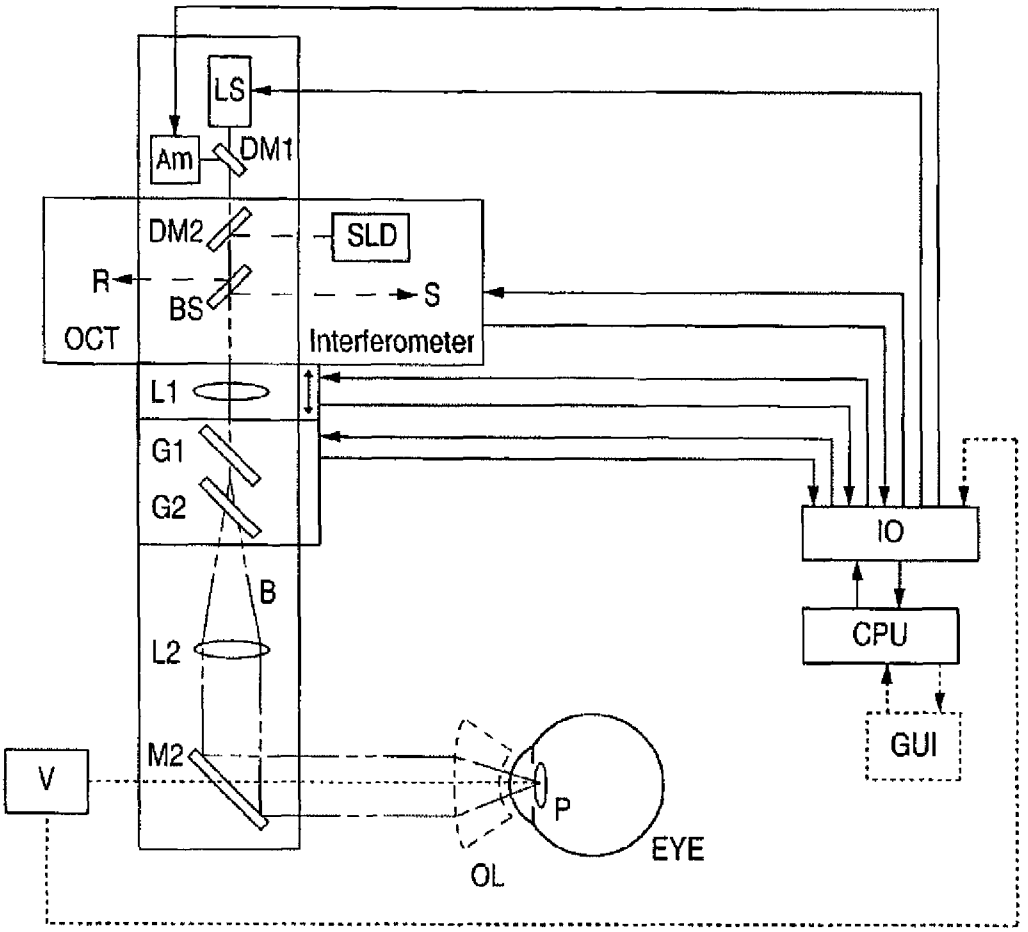


FIG. 11


LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
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IO
B
CPU
L2
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M2
V
P
EYE
OL

FIG. 12

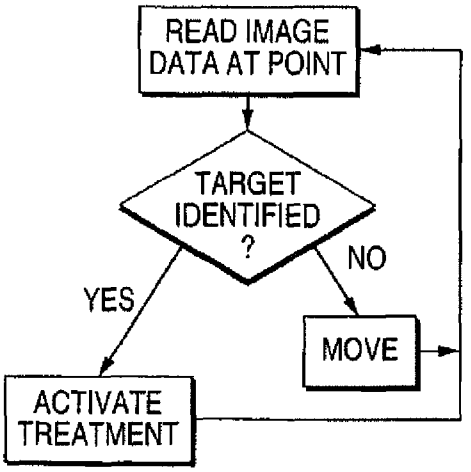
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

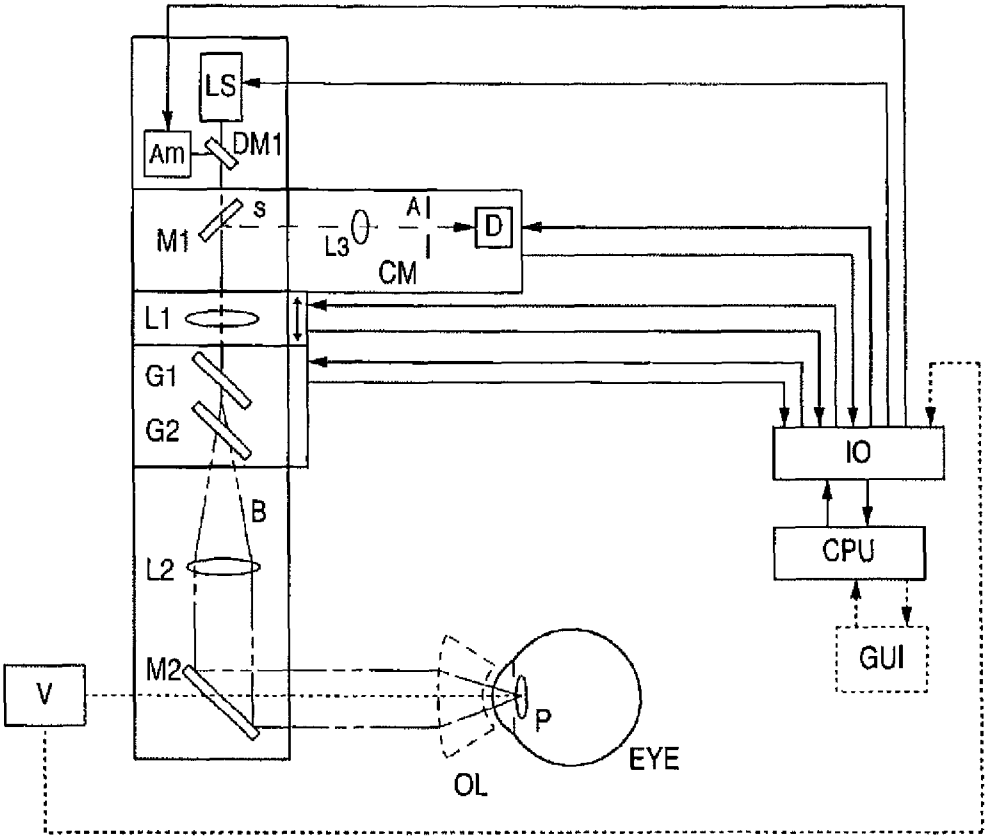

FIG. 13

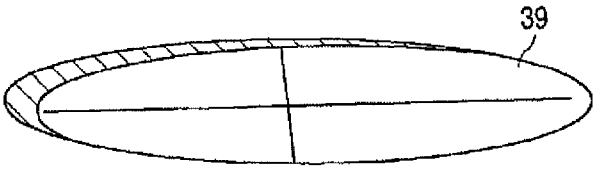

FIG. 16

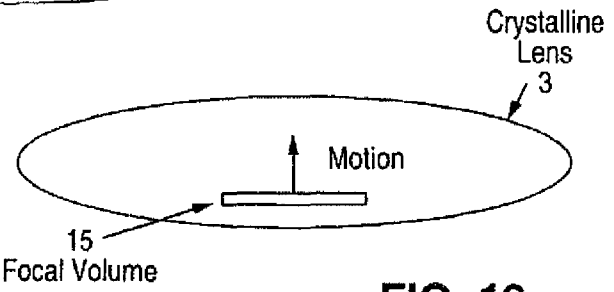

FIG. 19

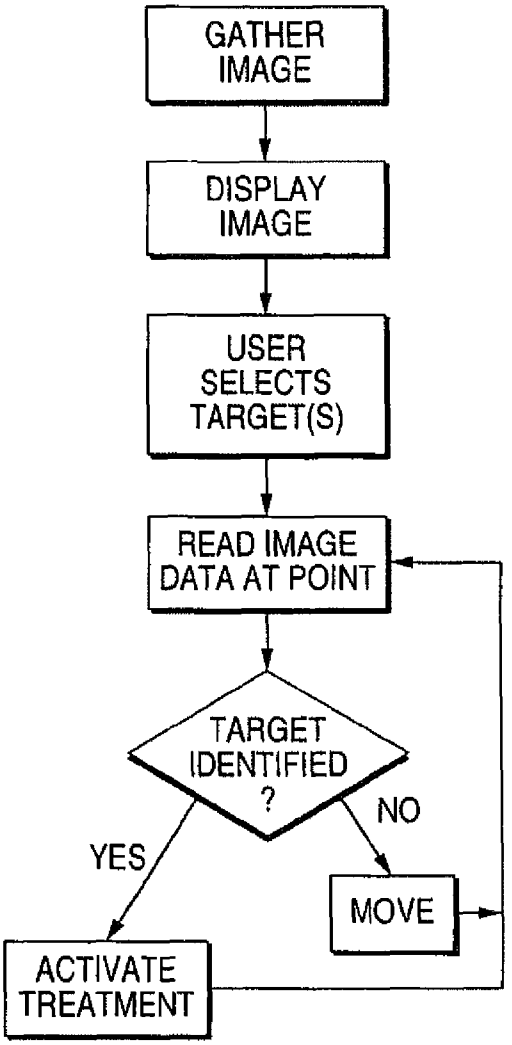
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

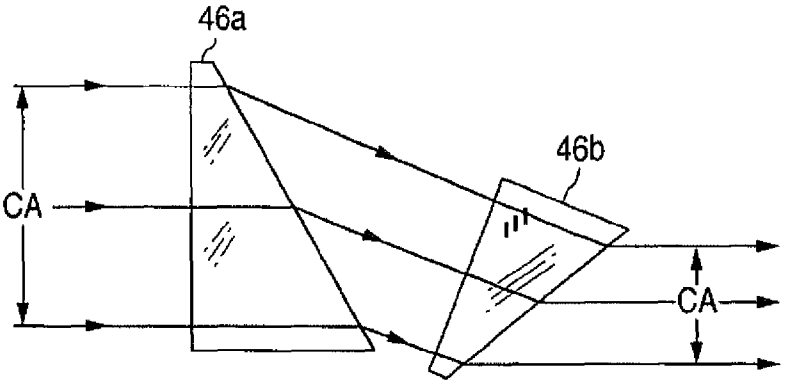
46a
46b
CA
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FIG. 18

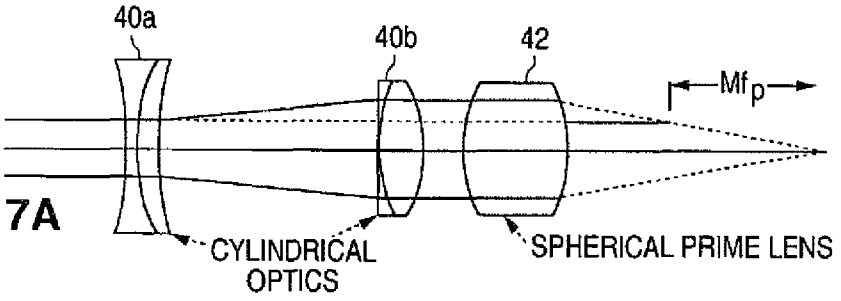

FIG. 17A

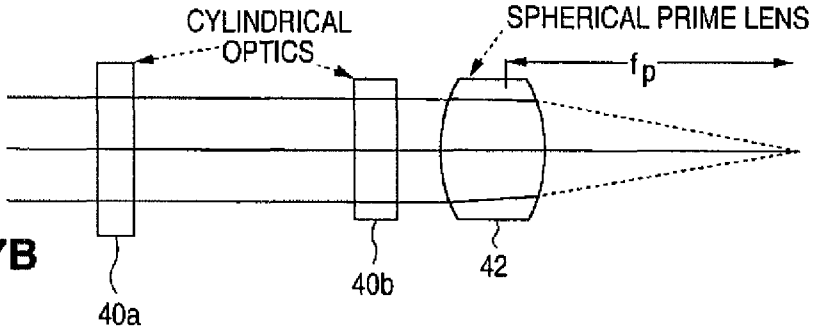

FIG. 17B

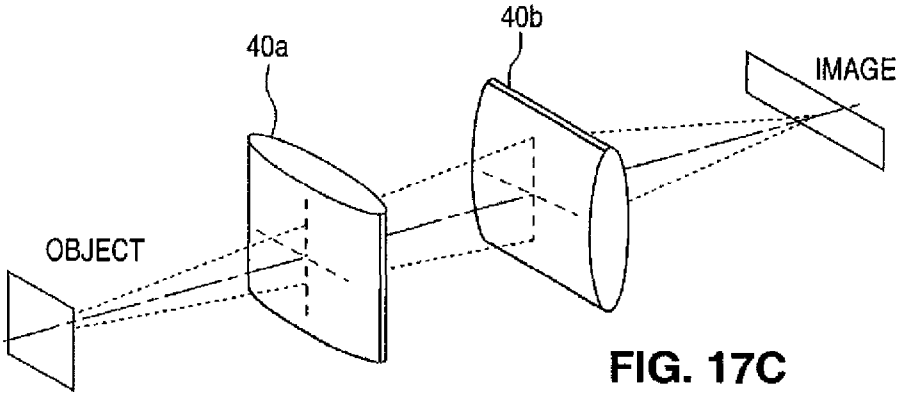

FIG. 17C

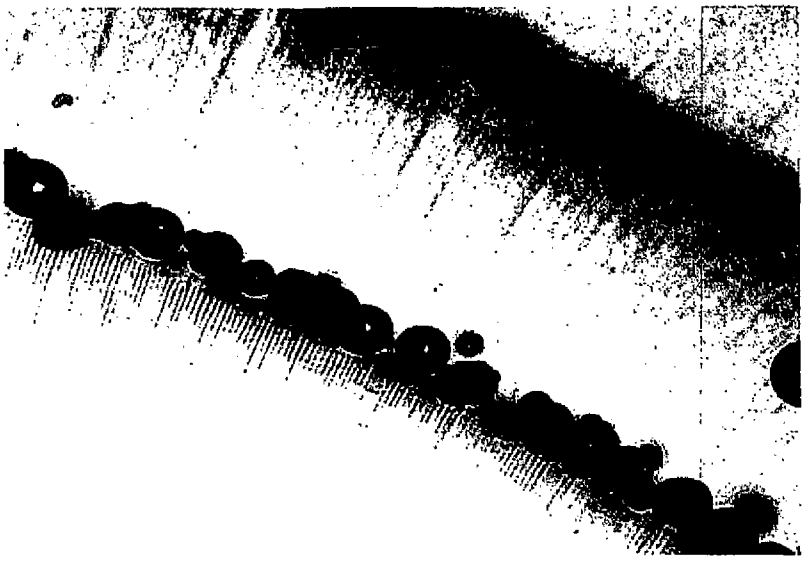

FIG. 20

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive* Surgery 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and

Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic. foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and

the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (1, 2, and 3) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F1, F2, F3.

FIG. **8** is an axial array of fibers (1, 2, 3) focused with a set of lenses into multiple points (1, 2, 3) and thus producing plasma at different depths inside the tissue (1, 2, 3).

FIG. **9**A and FIG. **9**B are diagrams illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ prep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue 2 will produce dielectric breakdown at the focal point, rupturing the

tissue 2 in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and λ is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda/(2\cdot NA)\approx\lambda F/D_b$15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R=1675$ to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4=176$ μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L\sim\lambda(4\cdot NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial

length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of

cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device IO and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and

expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595 patent, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and

tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μl, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that

various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A laser surgical system for making incisions in ocular tissue during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue, and an imaging device; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data for ocular tissue of a patient's eye, the image data including lens interior image data for an interior portion of the lens of the patient's eye;

process the image data to determine an anterior capsulotomy scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsulotomy; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern to perform the anterior capsulotomy,

wherein positioning of the focal zone is guided by the control system based on the image data.

2. The system of claim **1**, wherein the laser beam has a wavelength between 800 nm and 1,100 nm.

3. The system of claim **1**, wherein the laser beam comprises pulses having pulse energy between 1.0 micro joules and 1,000 micro joules.

4. The system of claim **3**, wherein the laser beam comprises pulses having pulse energy between 1.0 micro joules and 30 micro joules.

5. The system of claim **1**, wherein the laser beam comprises pulses having a pulse duration between about 100 femtoseconds and about 10 picoseconds.

6. The system of claim **1**, wherein the laser beam comprises pulses having a repetition rate between 1 kHz and about 200 kHz.

7. The system of claim **1**, wherein the anterior capsulotomy scanning pattern is configured to scan the focal zone to different depths, and wherein the focal zone is first scanned at a maximum depth and then scanned to sequentially shallower depths.

8. The system of claim **1**, wherein the control system is configured to scan the focal zone of the laser beam to segment the lens into discrete fragments.

9. The system of claim **8**, wherein the discrete fragments are sized to be removable through a lumen of an ophthalmic aspiration probe.

10. The system of claim **8**, wherein the control system is configured to control the laser and the scanning assembly to segment the lens into the discrete fragments by scanning the focal zone in one or more lens fragmentation scanning patterns.

11. The system of claim **10**, wherein the one or more lens fragmentation scanning patterns include at least one of a linear pattern, a planar pattern, a radial pattern, a circular pattern, a spiral pattern, a curvilinear pattern, or two or more overlapping line segments.

12. The system of claim **10**, wherein:

scanning the focal zone in the one or more lens fragmentation scanning patterns comprises sequentially applying laser pulses to different depths within the lens; and

the laser pulses are first applied at a maximum depth within the lens and then applied to sequentially shallower depths within the lens.

13. The system of claim **1**, wherein:

the scanning assembly comprises a z-axis scanning device and a transverse scanning device, the z-axis device being operable to change the location of the focal zone of the laser beam parallel to the direction of propagation of the laser beam, the transverse scanning device being operable to scan the location of the focal zone transverse to the direction of propagation of the laser beam; and

the scanning assembly is configured such that the laser beam is acted upon by the z-axis scanning device before being acted upon by the transverse scanning device.

14. The system of claim **13**, wherein:

the z-axis scanning device comprises one or more movable lenses; and

the transverse scanning device comprises one or more controllable scanning elements.

15. The system of claim **1**, wherein the control system is configured to:

process the image data to determine one or more axial locations of the anterior capsule of the lens; and

determine the anterior capsulotomy scanning pattern based on the one or more anterior capsule axial locations.

16. The system of claim **15**, wherein the control system is configured to determine a posterior cutting boundary for the anterior capsulotomy scanning pattern based on the one or more anterior capsule axial locations.

17. The system of claim **16**, wherein the control system is configured to determine an anterior cutting boundary for the anterior capsulotomy scanning pattern based on the one or more anterior capsule axial locations.

18. The system of claim **1**, wherein the control system configures the anterior capsulotomy scanning pattern based in part on an input from a user interface.

19. The system of claim **1**, wherein control system controls one or more parameters of the laser beam based on an input from a user interface.

20. The system of claim **19**, wherein the one or more laser beam parameters are selected from the group consisting of pulse energy, pulse repetition rate, pulse duration, and wavelength.

* * * * *

EXHIBIT H

US009107732B2

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Blumenkranz et al.

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(45) **Date of Patent: *Aug. 18, 2015**

(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

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This patent is subject to a terminal disclaimer.

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(58) **Field of Classification Search**

USPC 606/4, 5, 11, 15, 16

See application file for complete search history.

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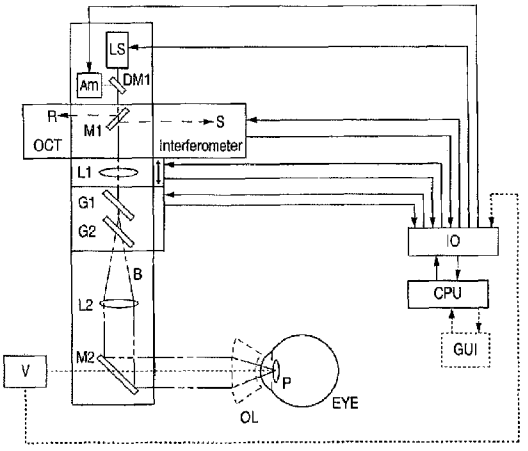
(57) **ABSTRACT**

System and method for making incisions in eye tissue at different depths. The system and method focuses light, possibly in a pattern, at various focal points which are at various depths within the eye tissue. A segmented lens can be used to create multiple focal points simultaneously. Optimal incisions can be achieved by sequentially or simultaneously focusing lights at different depths, creating an expanded column of plasma, and creating a beam with an elongated waist.

35 Claims, 10 Drawing Sheets



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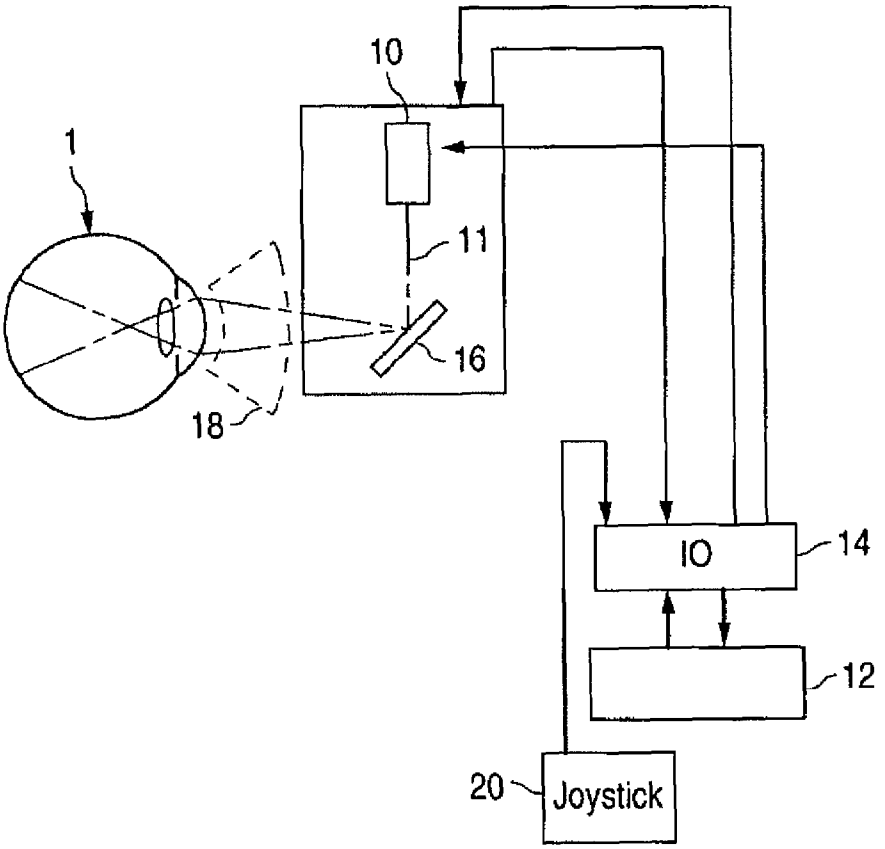

FIG. 1

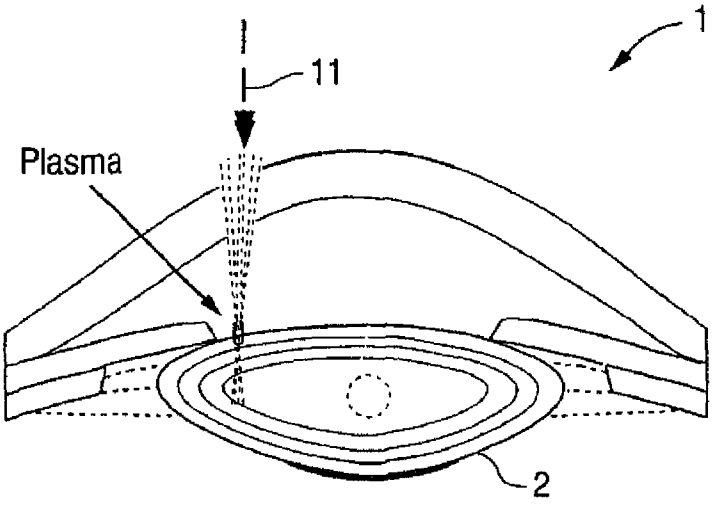

FIG. 2

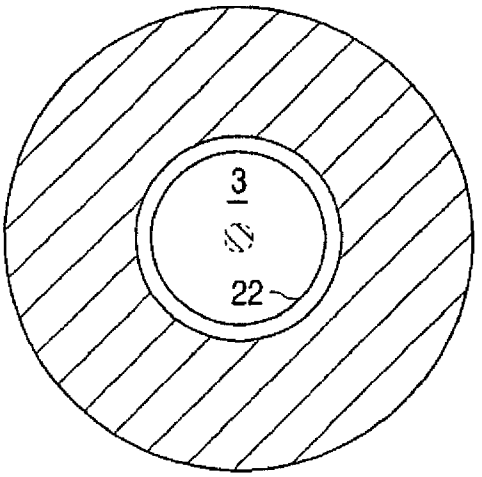

FIG. 3

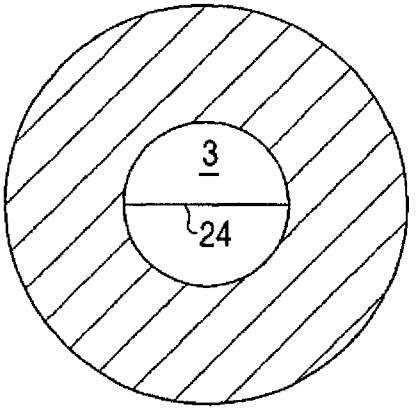

FIG. 4

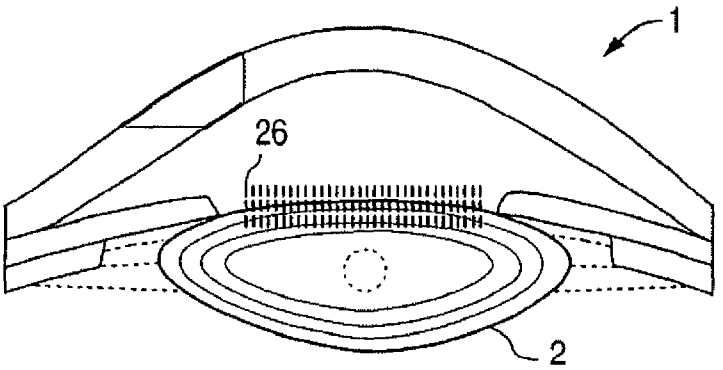

FIG. 5

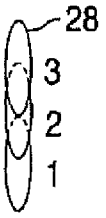

FIG. 6

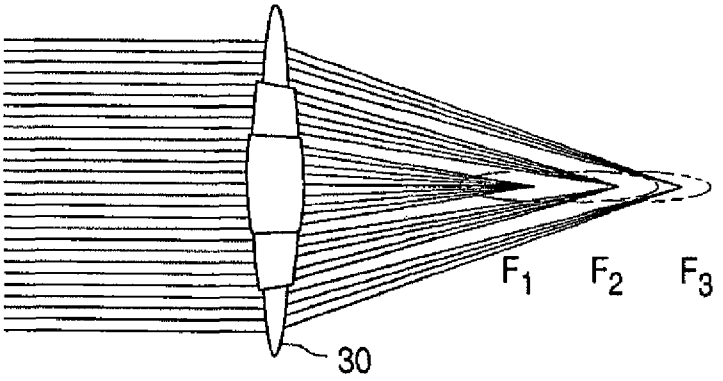

FIG. 7A

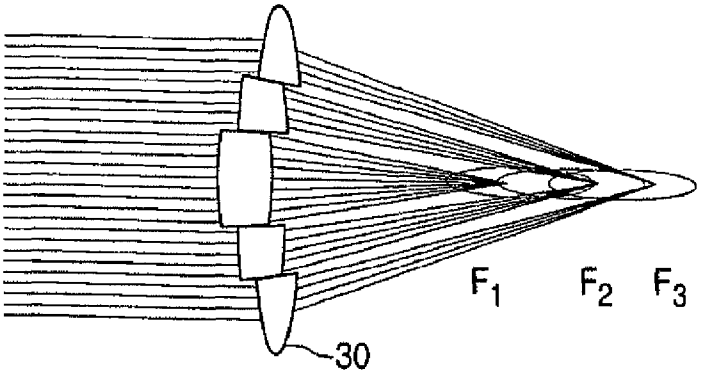

FIG. 7B

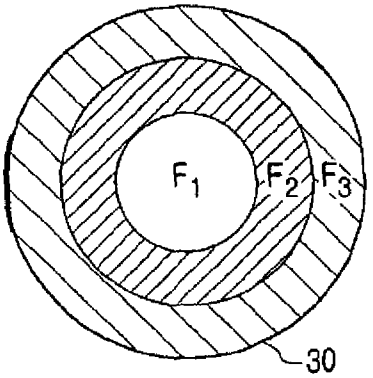

FIG. 7C

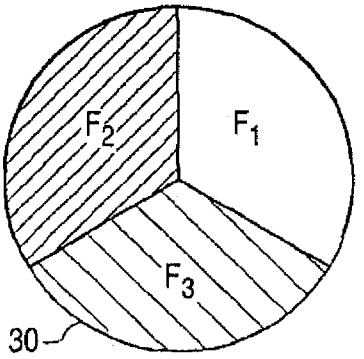

FIG. 7D

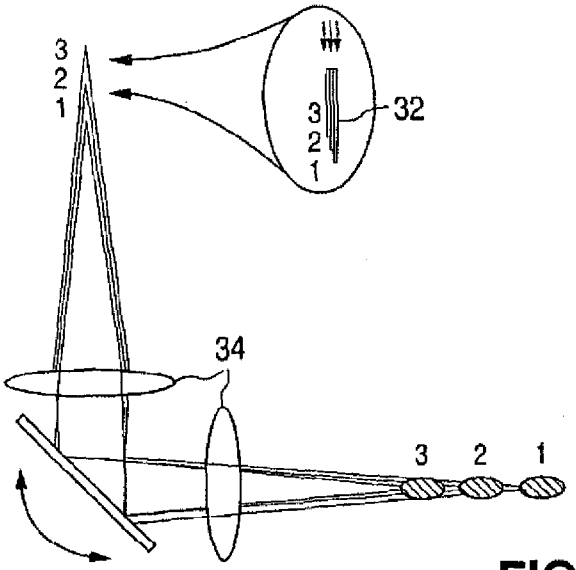

FIG. 8

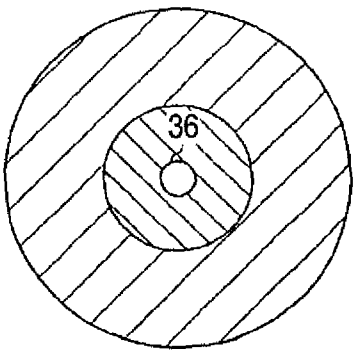

FIG. 9A

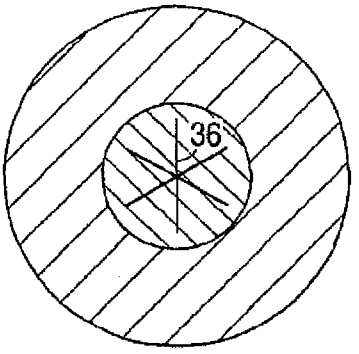

FIG. 9B

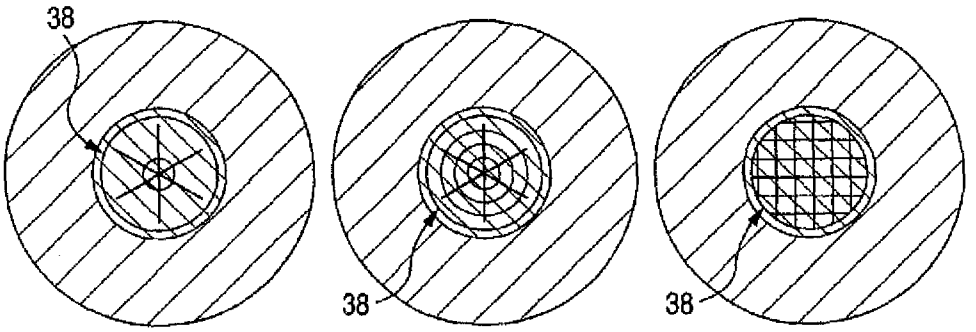

FIG. 10A FIG. 10B FIG. 10C

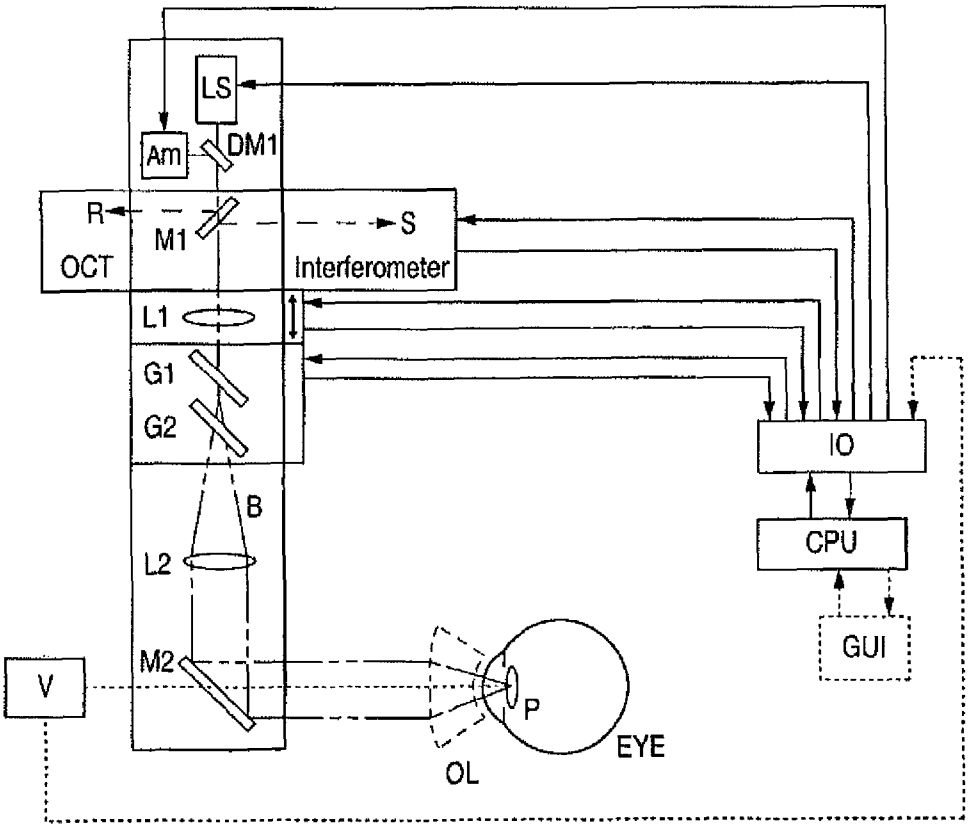

FIG. 11

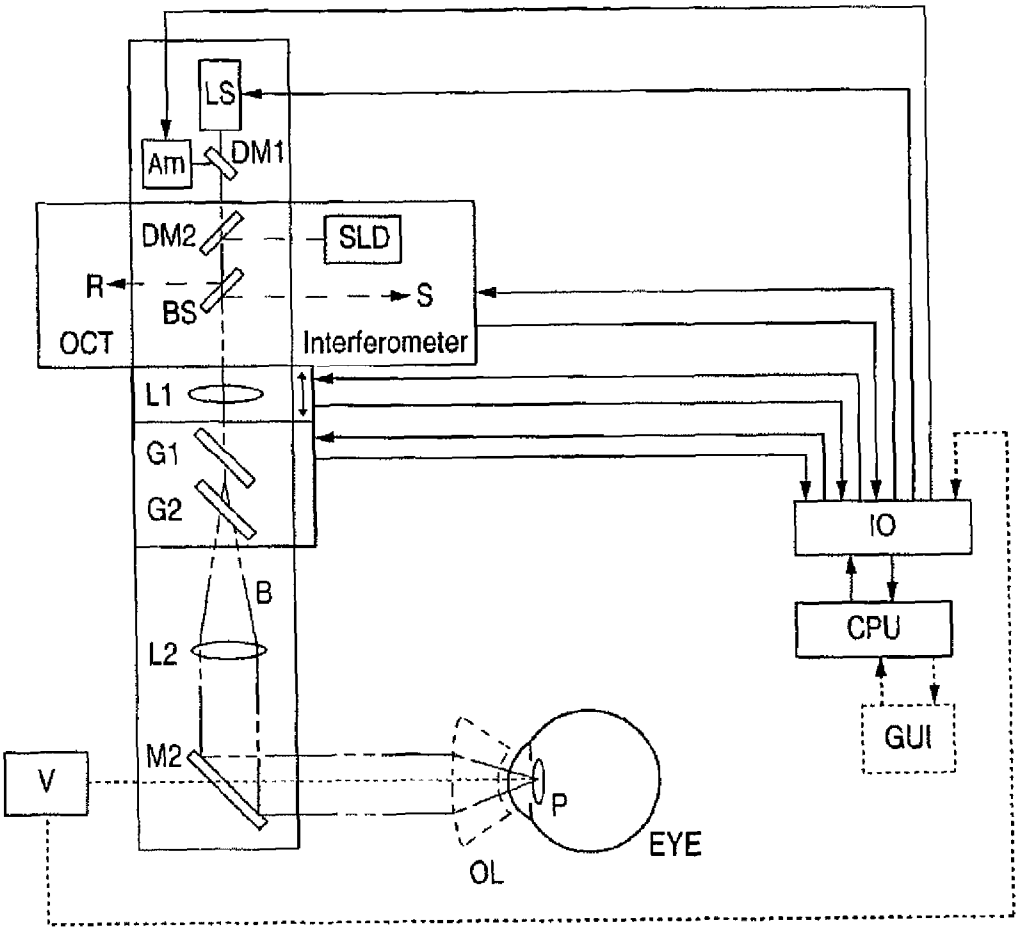
LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

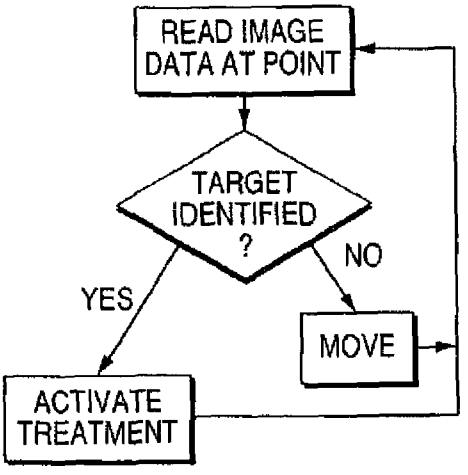
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

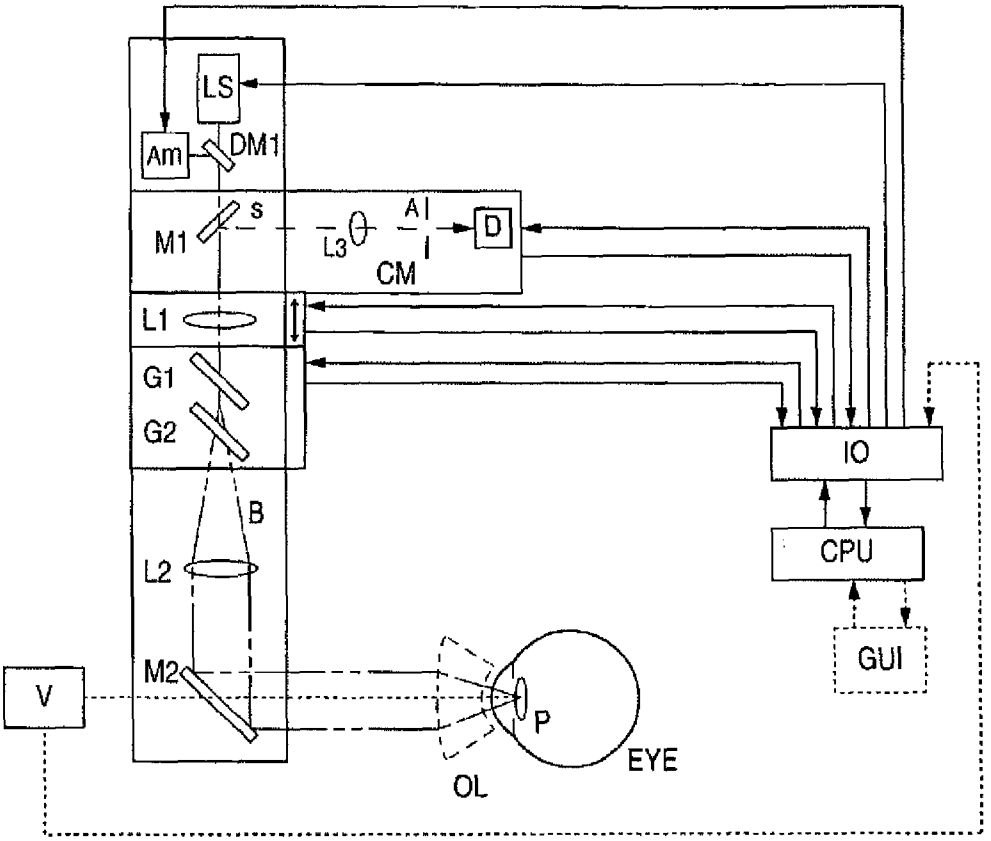

FIG. 13

FIG. 16

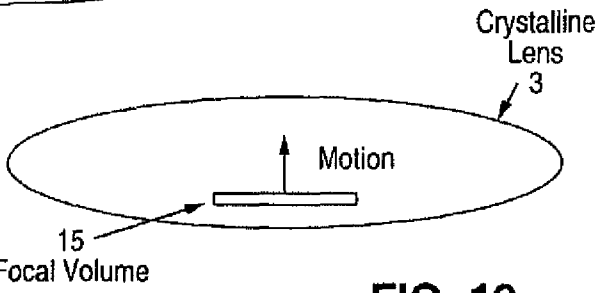

FIG. 19

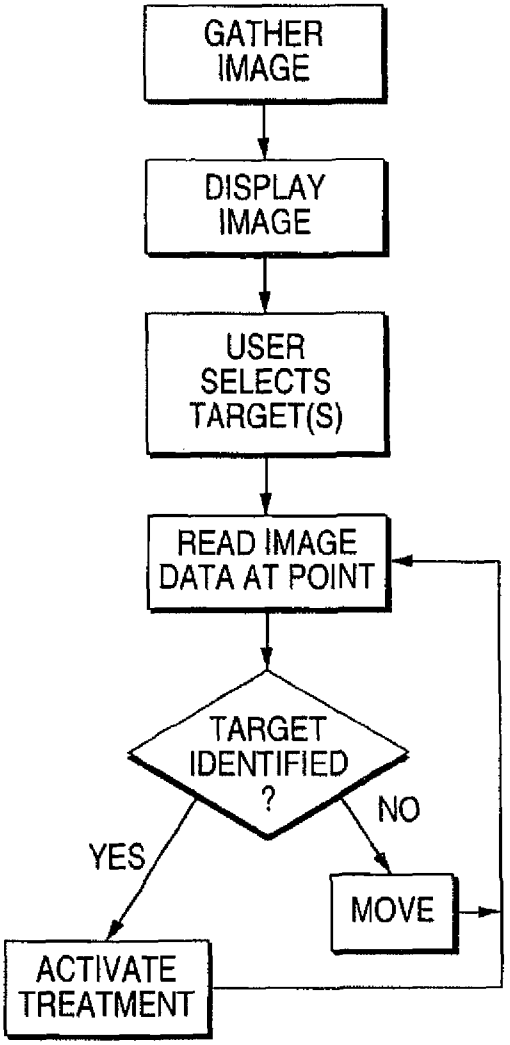
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

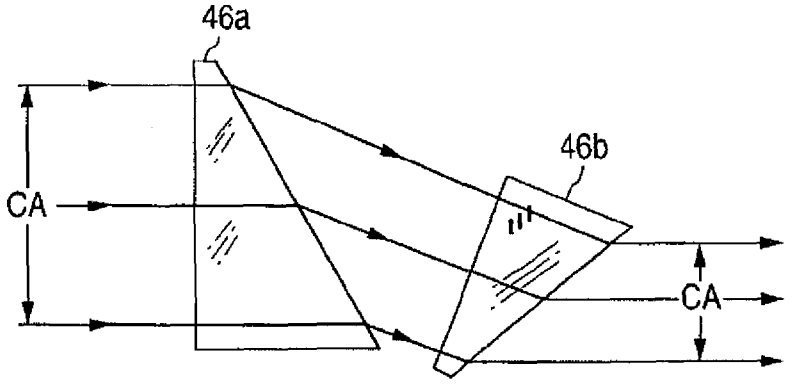
46a
46b
CA
CA

FIG. 18

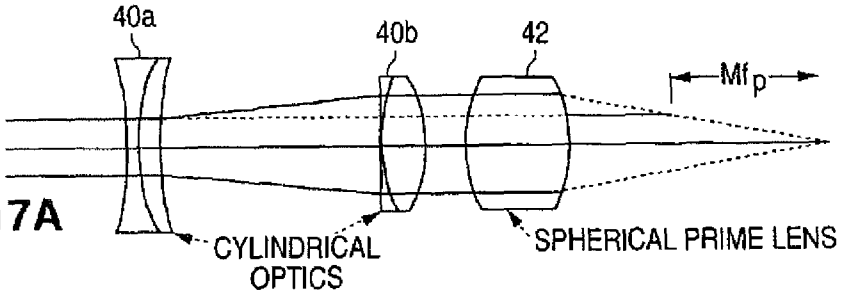

FIG. 17A

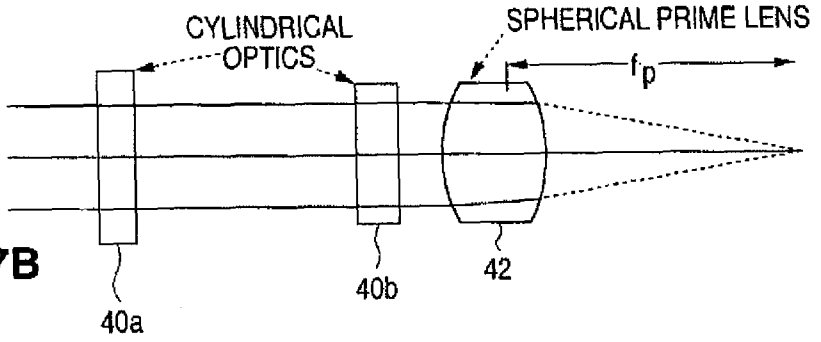

FIG. 17B

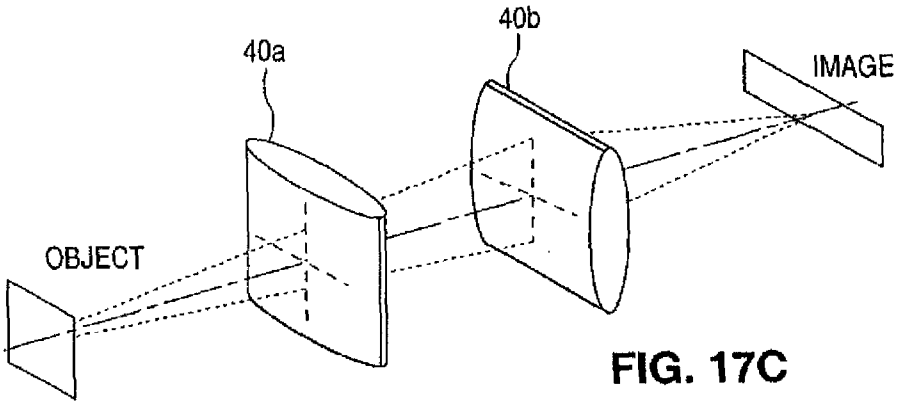

FIG. 17C

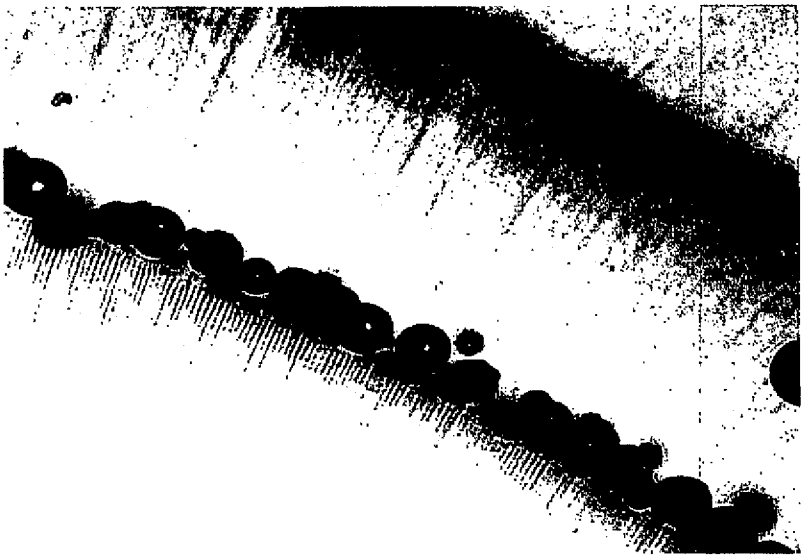

FIG. 20

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 13/588,966, filed Aug. 17, 2012, which is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of all of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is

illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special

circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic. foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto

the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (1, 2, and 3) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F1, F2, F3.

FIG. **8** is an axial array of fibers (1, 2, 3) focused with a set of lenses into multiple points (1, 2, 3) and thus producing plasma at different depths inside the tissue (1, 2, 3).

FIG. **9**A and FIG. **9**B are diagrams illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue 2 will produce dielectric breakdown at the focal point, rupturing the

tissue 2 in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and λ is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L\sim\lambda/(4\cdot NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial

length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of

cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device IO and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device TO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and

expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and

tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that

various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A laser surgical system for making incisions in ocular tissue during a cataract surgical procedure, the system comprising:

a laser operable to generate a laser beam for incising ocular tissue;

a scanning assembly operable to direct a focal zone of the laser beam to locations within a patient's eye;

an optical coherence tomography (OCT) imaging device; and

a control system operably coupled to the laser, the scanning assembly, and the OCT imaging device; the control system being configured to:

operate the OCT imaging device to generate image data for ocular tissue of the patient, the image data including lens interior image data for an interior portion of the lens of the patient's eye;

process the image data to determine an anterior capsulotomy scanning pattern for scanning the focal zone of the laser beam for performing an anterior capsulotomy; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is guided by the control system based on the image data.

2. The system of claim **1**, wherein the laser beam has a wavelength between 800 nm and 1,100 nm, wherein the laser beam comprises pulses having pulse energy between 1.0 micro joules and 30 micro joules, wherein the laser beam comprises pulses having a pulse duration between about 100 femtoseconds and about 10 picoseconds, and wherein the laser beam comprises pulses having a repetition rate between 1 kHz and about 200 kHz.

3. The system of claim **1**, wherein the laser beam is used to incise ocular tissue and to provide a sample input and a reference input to the OCT imaging device to generate the image data.

4. The system of claim **3**, wherein the scanning assembly is used to scan the laser beam in ocular tissues so as to provide the sample input to the OCT imaging device to generate the image data.

5. The system of claim **4**, wherein:

the control system is configured to control the scanning assembly to scan the laser beam relative to the lens to provide the sample input to the OCT imaging device to generate three-dimensional location data for the anterior capsule of the lens of the patient's eye; and

the control system is configured to determine the anterior capsulotomy scanning pattern based on the three-dimensional location data for the anterior capsule.

6. The system of claim **5**, wherein the laser beam is scanned across the lens to provide the sample input to the OCT imaging device to the generate three-dimensional location data for the anterior capsule.

7. The system of claim **4**, wherein:

the scanning assembly comprises a z-axis scanning device and a transverse scanning device, the z-axis device being operable to move the focal zone of the laser beam parallel to the direction of propagation of the laser beam, the transverse scanning device being operable to scan the location of the focal zone transverse to the direction of propagation of the laser beam; and

the laser beam propagates along an optical path in which the z-axis scanning device is disposed between the OCT imaging device and the transverse scanning device.

8. The system of claim **1**, wherein the OCT imaging device includes an imaging light source that output imaging light used to provide a sample input and a reference input to the OCT imaging device to generate the image data.

9. The system of claim **8**, wherein the imaging light has a range of wavelengths about 50 nm wide and centered on or around 835 nm.

10. The system of claim **8**, wherein the scanning assembly is used to scan the imaging light in ocular tissues so as to provide the sample input to the OCT imaging device to generate the image data.

11. The system of claim **10**, wherein:

the control system is configured to control the scanning assembly to scan the imaging light relative to the lens to provide the sample input to the OCT imaging device to generate three-dimensional location data for the anterior capsule of the lens of the patient's eye; and

the control system is configured to determine the anterior capsulotomy scanning pattern based on the three-dimensional location data for the anterior capsule.

12. The system of claim **11**, wherein the imaging light is scanned across the lens to provide the sample input to the OCT imaging device to the generate three-dimensional location data for the anterior capsule.

13. The system of claim **10**, wherein:

the scanning assembly comprises a z-axis scanning device and a transverse scanning device, the z-axis device being operable to move a focal zone of the imaging light parallel to the direction of propagation of the imaging light, the transverse scanning device being operable to scan the location of the focal zone of the imaging light transverse to the direction of propagation of the imaging light; and

the imaging light propagates along an optical path in which the z-axis scanning device is disposed between the OCT imaging device and the transverse scanning device.

14. The system of claim **1**, wherein the OCT imaging device employs time domain OCT or frequency domain OCT.

15. A method for incising ocular tissue during a cataract surgical procedure, the method comprising:

operating an optical coherence tomography (OCT) imaging device to generate image data of ocular tissue, the image data including lens interior image data for an interior portion of the lens of a patient's eye;

processing the image data via a control system so as to generate an anterior capsulotomy scanning pattern for scanning a focal zone of a laser beam for performing an anterior capsulotomy, the OCT imaging device being operatively coupled to the control system;

generating the laser beam; and

scanning the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is controlled by the control system based on the image data.

16. The method of claim **15**, wherein the laser beam has a wavelength between 800 nm and 1,100 nm, wherein the laser beam comprises pulses having pulse energy between 1.0 micro joules and 30 micro joules, wherein the laser beam comprises pulses having a pulse duration between about 100

femtoseconds and about 10 picoseconds, and wherein the laser beam comprises pulses having a repetition rate between 1 kHz and about 200 kHz.

17. The method of claim **15**, further comprising using the laser beam to provide a sample input and a reference input to the OCT imaging device to generate the image data.

18. The method of claim **17**, further comprising scanning the laser beam in ocular tissue so as to provide the sample input to the OCT imaging device to generate the image data.

19. The method of claim **18**, wherein the laser beam is scanned across the lens to provide the sample input to the OCT imaging device to generate the image data.

20. The method of claim **17**, further comprising:

processing the image data via the control system to generate three-dimensional location data for the anterior capsule of the lens; and

generating the anterior capsulotomy scanning pattern based on the three-dimensional location data for the anterior capsule.

21. The method of claim **18**, wherein said scanning the laser beam in ocular tissue so as to provide the sample input to the OCT imaging device to generate the image data comprises:

operating a z-axis scanning device to move the focal zone of the laser beam parallel to the direction of propagation of the laser beam; and

operating a transverse scanning device to scan the focal zone of the laser beam transverse to the direction of propagation of the laser beam,

wherein the laser beam propagates along an optical path in which the z-axis scanning device is disposed between the OCT imaging device and the transverse scanning device.

22. The method of claim **15**, wherein the OCT imaging device includes an imaging light source that outputs imaging light used to provide a sample input and a reference input to the OCT imaging device to generate the image data.

23. The system of claim **22**, wherein the imaging light has a range of wavelengths about 50 nm wide and centered on or around 835 nm.

24. The method of claim **22**, further comprising scanning the imaging light in ocular tissue so as to provide the sample input to the OCT imaging device to generate the image data.

25. The method of claim **24**, wherein the imaging light is scanned across the lens to provide the sample input to the OCT imaging device to generate the image data.

26. The method of claim **22**, further comprising:

processing the image data via the control system to generate three-dimensional location data for the anterior capsule of the lens; and

generating the anterior capsulotomy scanning pattern based on the three-dimensional location data for the anterior capsule.

27. The method of claim **24**, wherein said scanning the imaging light in ocular tissue so as to provide the sample input to the OCT imaging device to generate the image data comprises:

operating a z-axis scanning device to move a focal zone of the imaging light parallel to the direction of propagation of the imaging light; and

operating a transverse scanning device to scan the focal zone of the imaging light transverse to the direction of propagation of the imaging light,

wherein the imaging light propagates along an optical path in which the z-axis scanning device is disposed between the OCT imaging device and the transverse scanning device.

28. The method of claim **15**, wherein the OCT imaging device employs time domain OCT or frequency domain OCT.

29. A cataract surgical procedure comprising:

operating an optical coherence tomography (OCT) imaging device to generate image data of ocular tissue, the image data including lens interior image data for an interior portion of the lens of a patient's eye;

processing the image data via a control system so as to generate an anterior capsulotomy scanning pattern for scanning a focal zone of a laser beam for performing an anterior capsulotomy, the OCT imaging device being operatively coupled to the control system;

generating the laser beam; and

scanning the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is controlled by the control system; and

ultrasonically breaking the lens into pieces.

30. The method of claim **29**, further comprising scanning the focal zone of the laser beam to segment the lens into discrete fragments prior to ultrasonically breaking the lens into pieces.

31. The method of claim **30**, wherein the discrete fragments are sized to be removable through a lumen of an ophthalmic aspiration probe.

32. The method of claim **30**, wherein scanning the focal zone of the laser beam to segment the lens into discrete fragments comprises scanning the focal zone in one or more lens fragmentation scanning patterns.

33. The method of claim **30**, wherein the one or more lens fragmentation scanning patterns include at least one of a linear pattern, a planar pattern, a radial pattern, a circular pattern, a spiral pattern, a curvilinear pattern, or two or more overlapping line segments.

34. The method of claim **29**, further comprising removing the pieces from the lens capsule.

35. The method of claim **34**, further comprising inserting into the lens capsule at least one of an intraocular lens and an optically transparent gel.

* * * * *

EXHIBIT I

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Blumenkranz et al.

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(54) **METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION**

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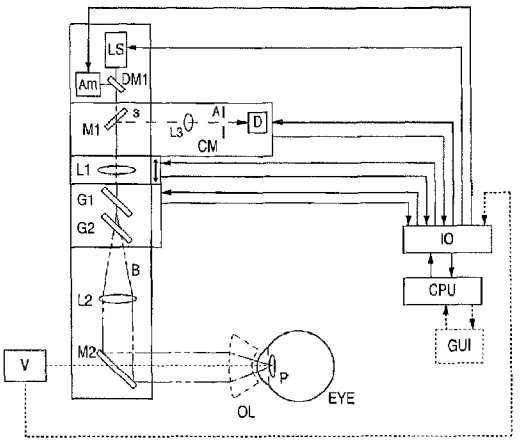
(57) **ABSTRACT**

A laser surgical system for making incisions in ocular tissues during cataract surgery includes a laser system, an imaging device and a control system. The laser system includes a scanning assembly and a laser to generate a laser beam that incises ocular tissue. The imaging device acquires image data of a crystalline lens and constructs an image from the image data. The control system operates the imaging device to generate image data for the patient's crystalline lens, processes the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam to perform an anterior capsule incision, and operates the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsule incision scanning pattern, wherein the focal zone is guided by the control system based on the image data.

13 Claims, 10 Drawing Sheets



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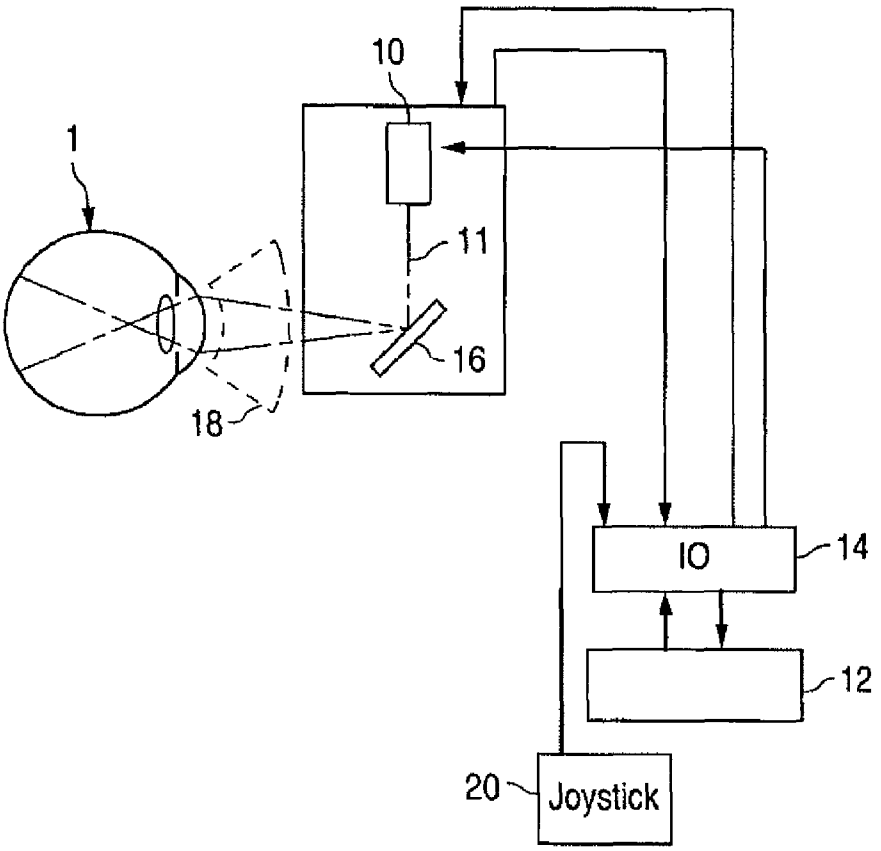
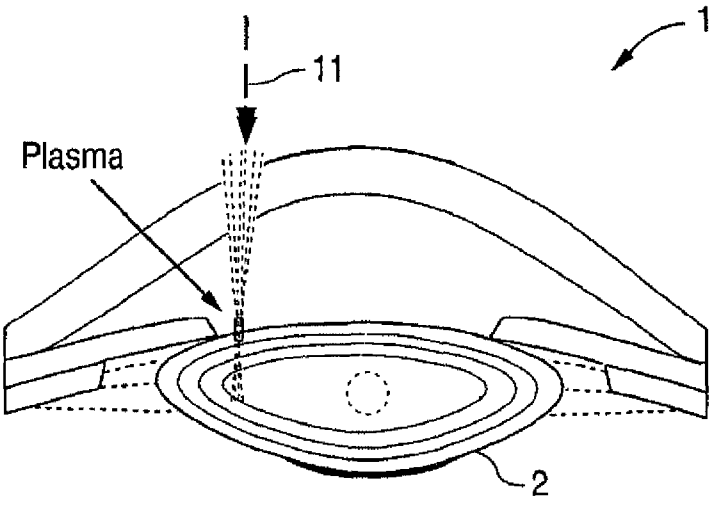


FIG. 1



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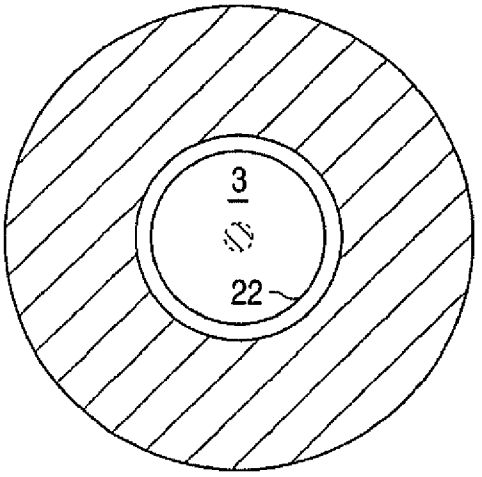

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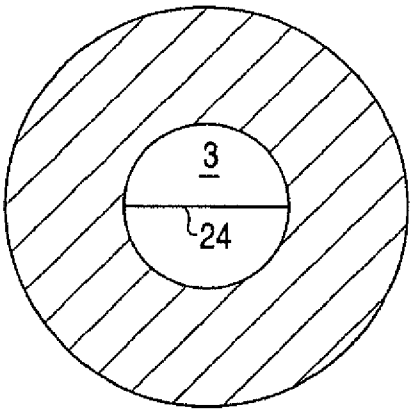

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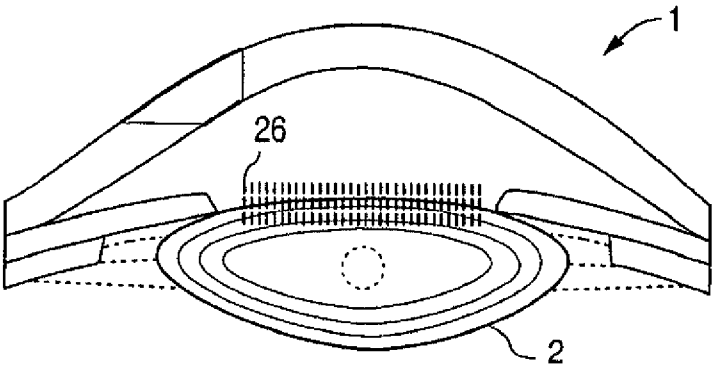
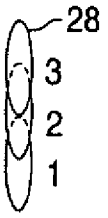


FIG. 5



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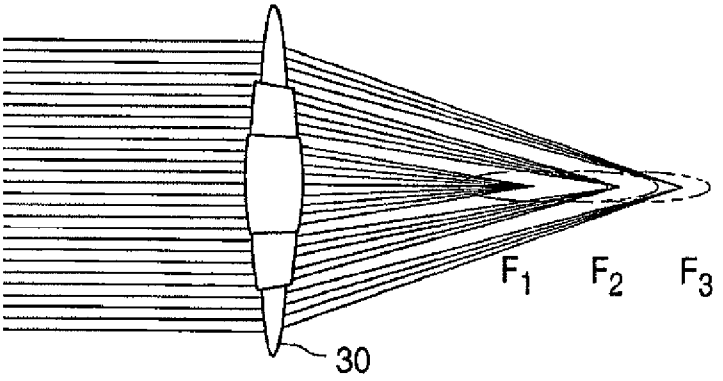


FIG. 7A

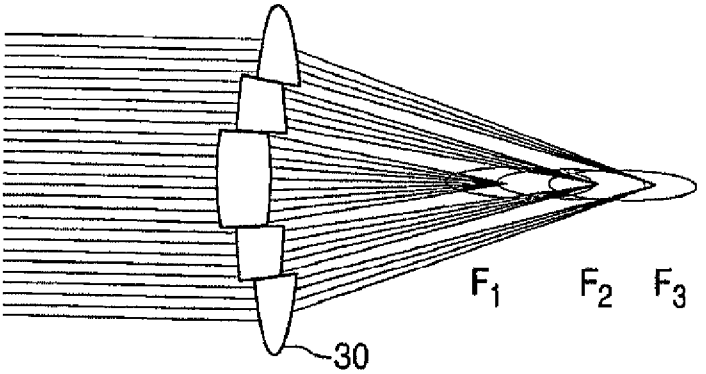


FIG. 7B

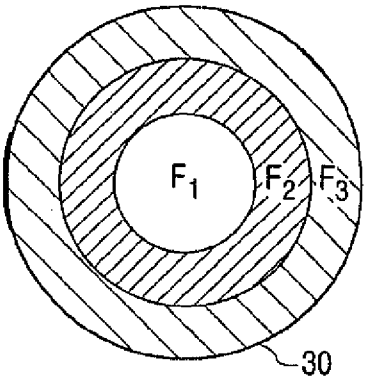
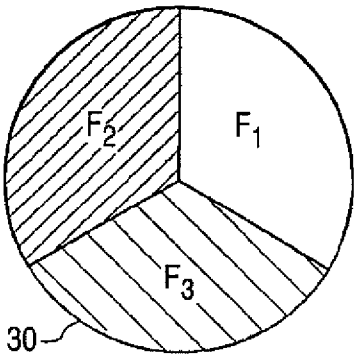


FIG. 7C



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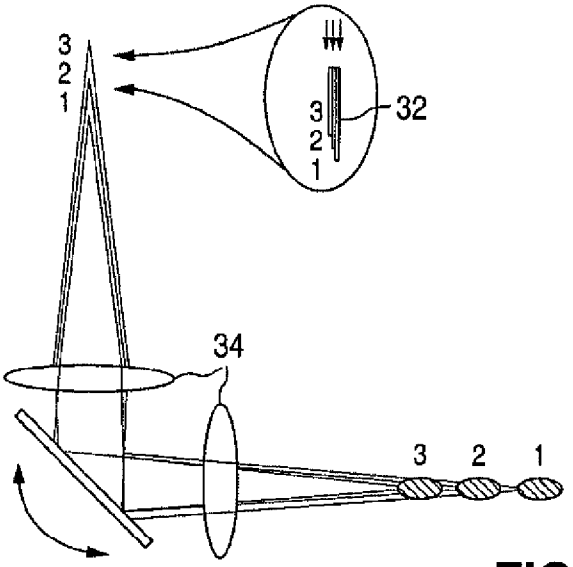


FIG. 8

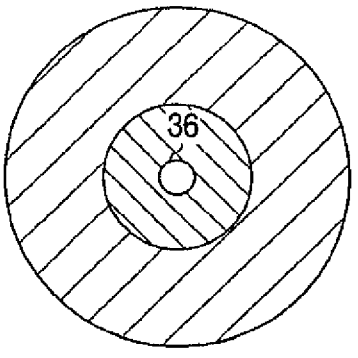


FIG. 9A

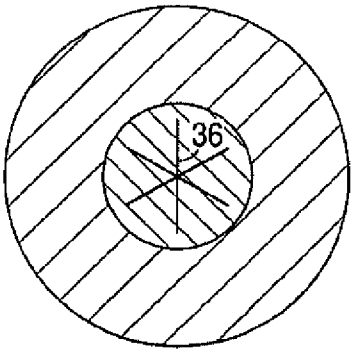


FIG. 9B

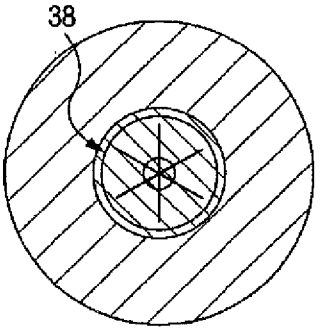
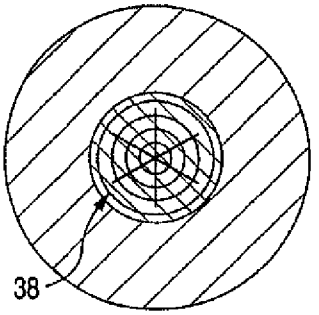


FIG. 10A



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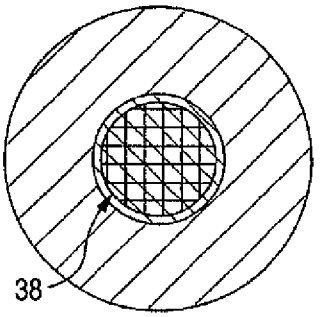


FIG. 10C

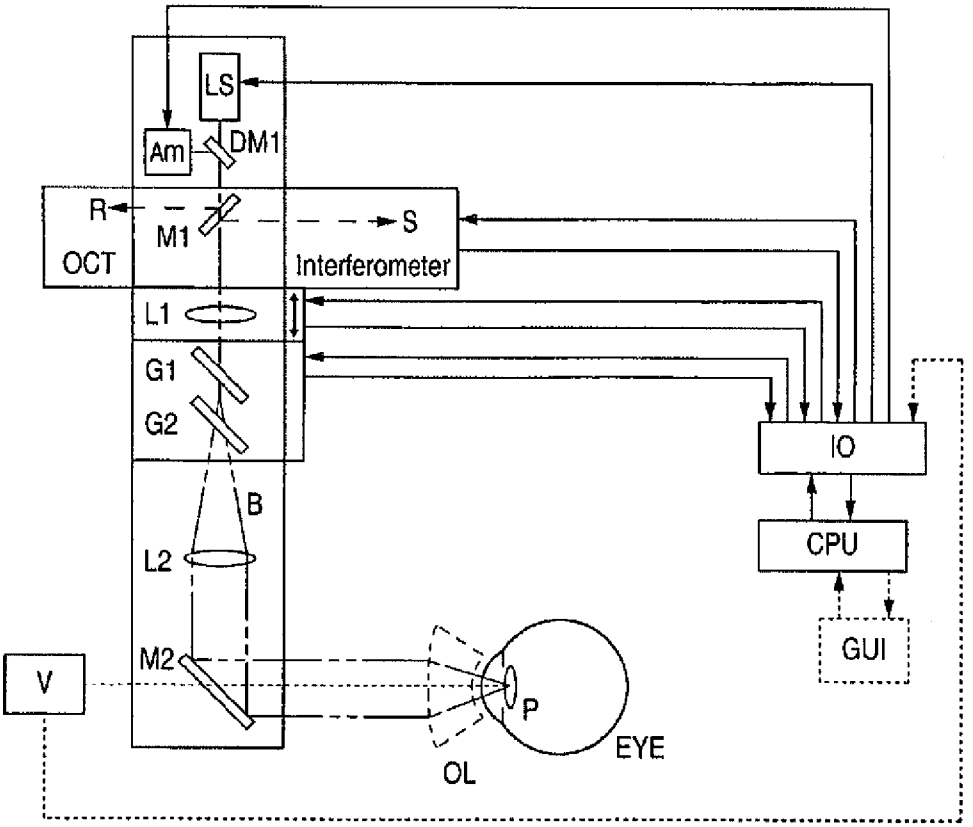
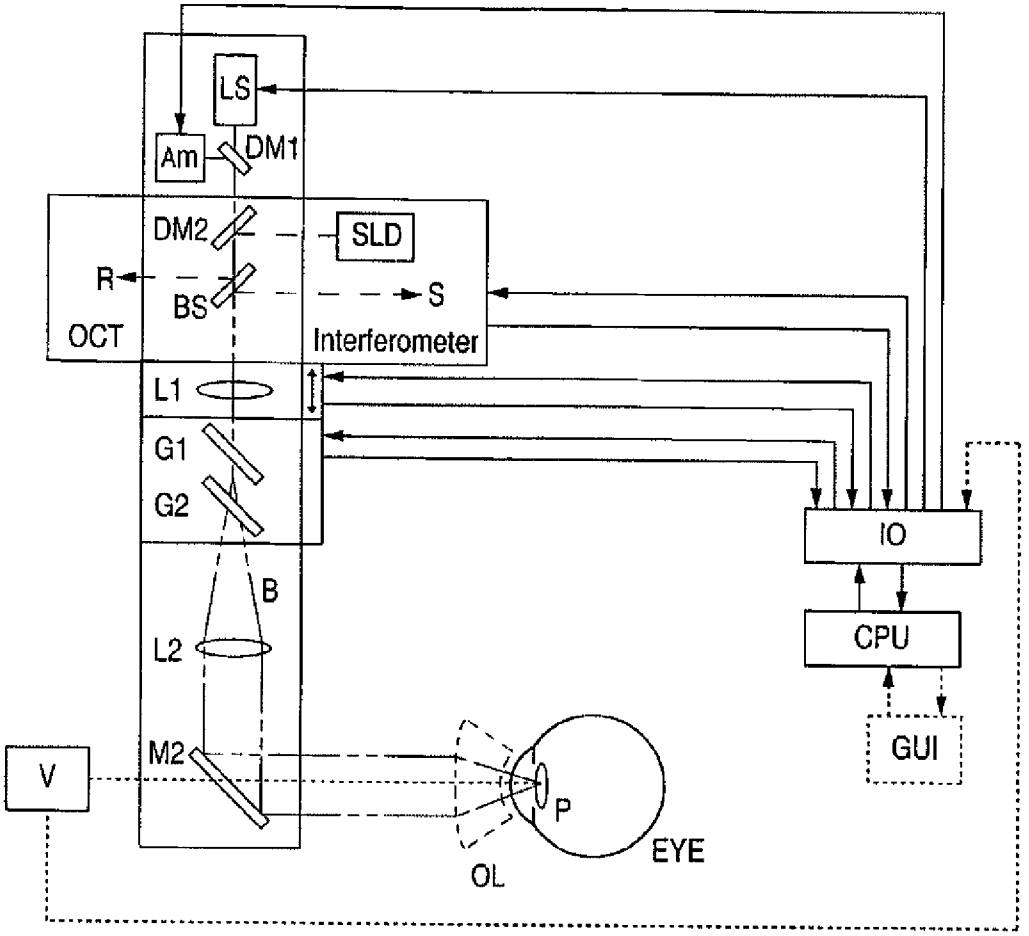


FIG. 11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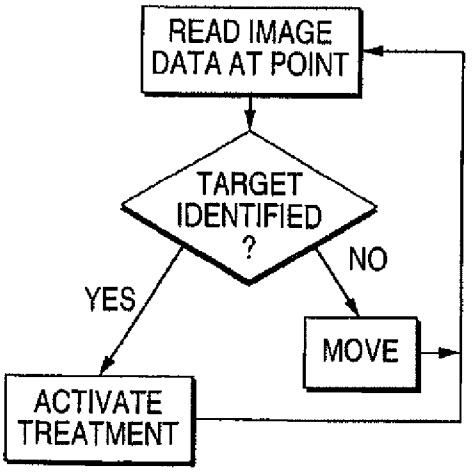
OL

FIG. 12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YES
MOVE
ACTIVATE TREATMENT

FIG. 14

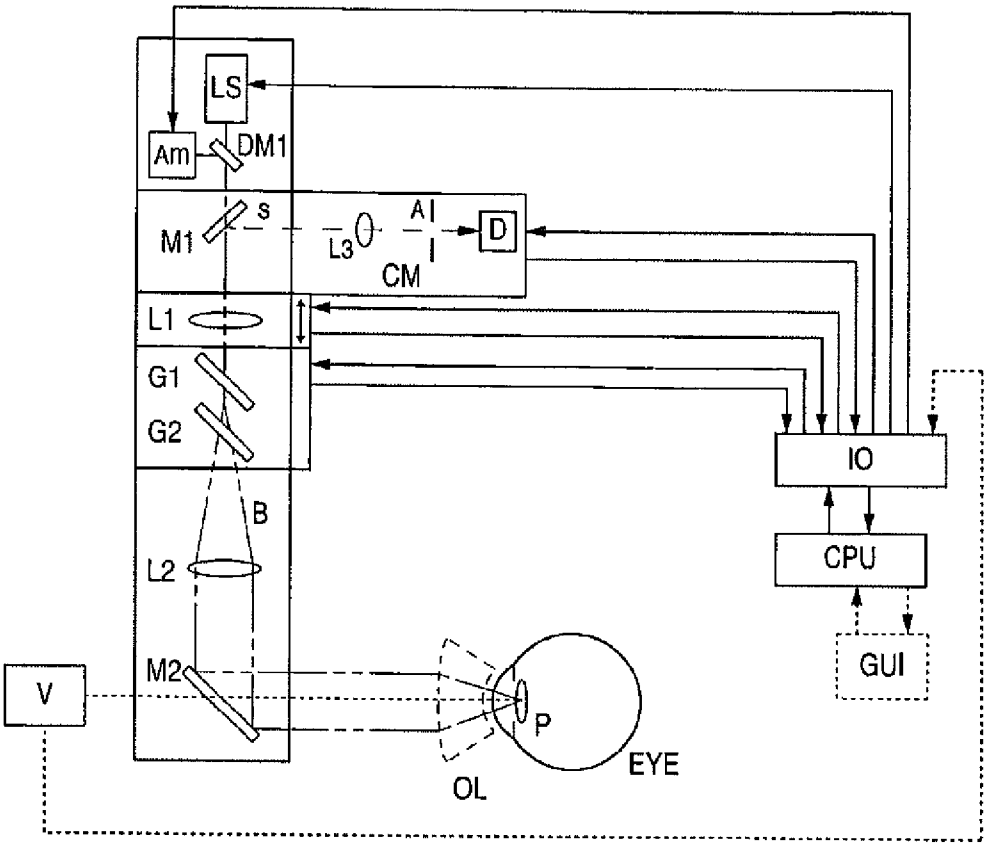

FIG. 13

FIG. 16

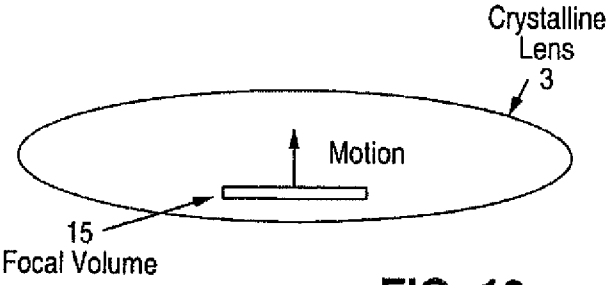

FIG. 19

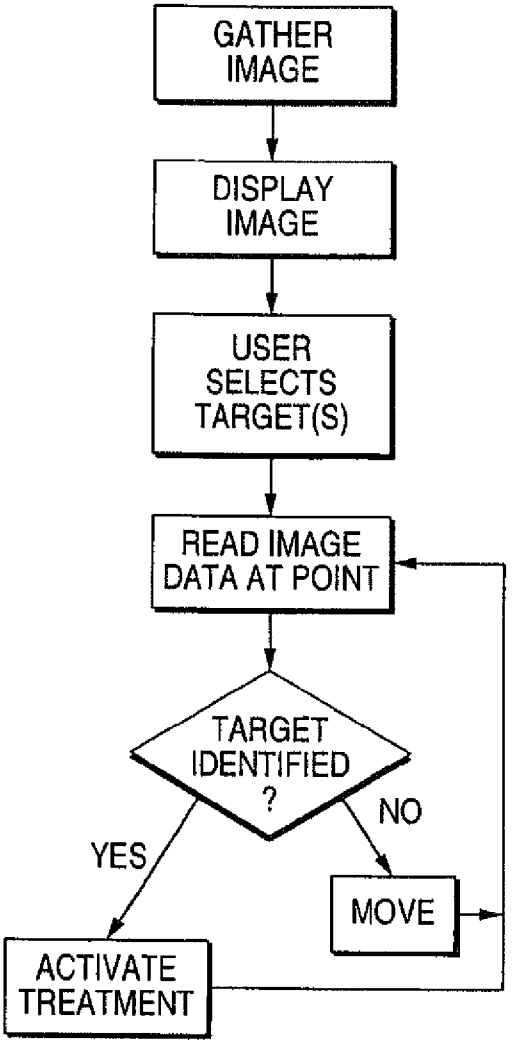
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
YES
NO
MOVE
ACTIVATE TREATMENT

FIG. 15

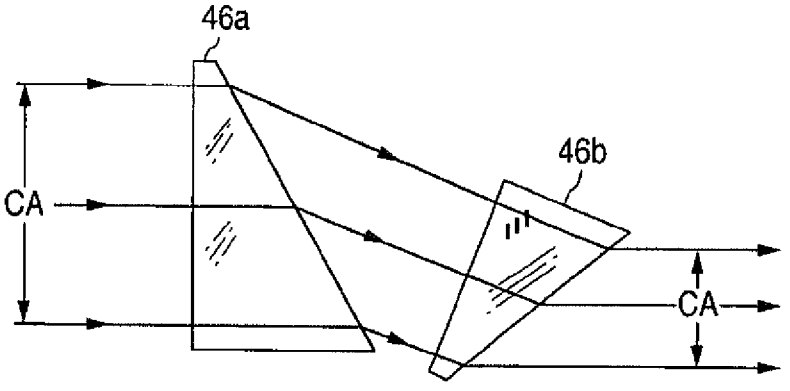
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FIG. 18

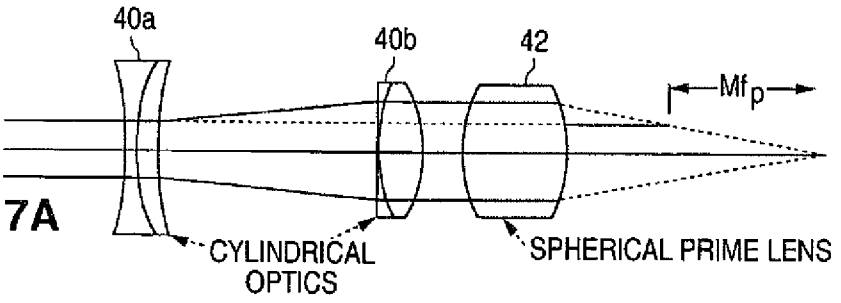

FIG. 17A

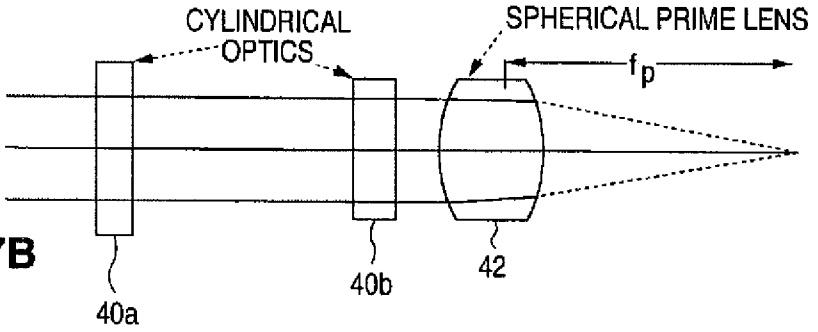

FIG. 17B

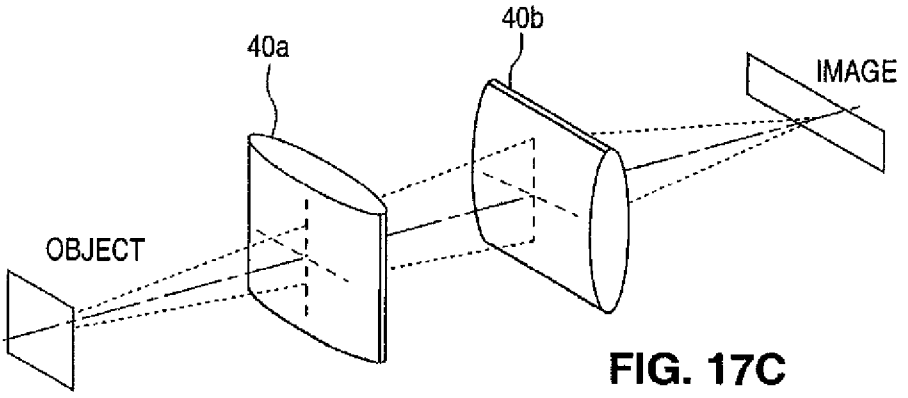

FIG. 17C

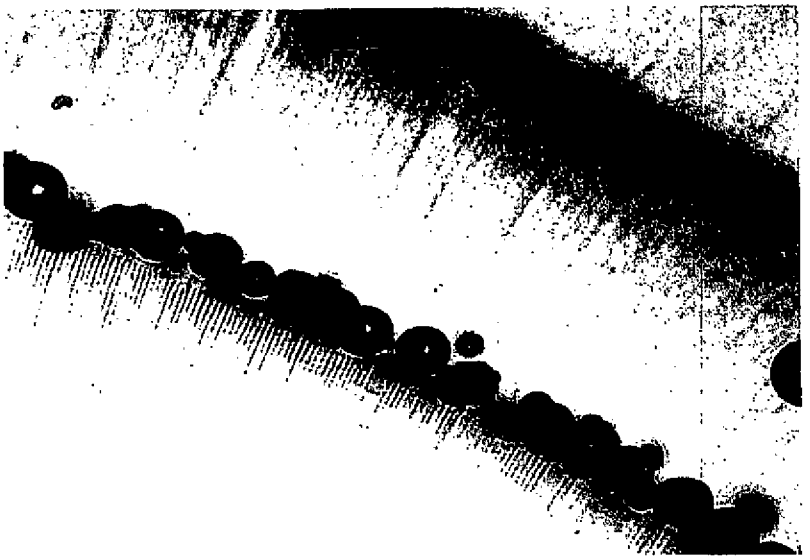

FIG. 20

FIG. 21

METHOD AND APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER TREPHINATION OF THE LENS CAPSULE AND THREE DIMENSIONAL PHACO-SEGMENTATION

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 14/184,047, filed Feb. 19, 2014, which is a continuation of U.S. patent application Ser. No. 13/588,966, filed Aug. 17, 2012, which is a continuation of U.S. Patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of all of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million eases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior

lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic. foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a

beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (1, 2, and 3) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (1, 2, 3) focused with a set of lenses into multiple points (1, 2, 3) and thus producing plasma at different depths inside the tissue (1, 2, 3).

FIG. **9**A and FIG. **9**B are diagrams illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy

not exceeding 100 μA at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and λ is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda/(2\cdot NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line 22 around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold, radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E_b=35 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L\sim\lambda/(4.NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (hi the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual

differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the seamier G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device **10** and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent

diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595 patent, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if

only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1× 1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 ml/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to

those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire point by point image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data for patient's crystalline lens;

process the image data to identify a location for each of one or more targets in the lens of the patient;

process the image data to determine a treatment scanning pattern for scanning a focal zone of the laser beam for performing one or more incisions in the lens capsule; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the treatment scanning pattern at each location of the one or more targets, wherein positioning of the focal zone is guided by the control system based on the location of the one or more targets so as to perform the one or more incision in the lens capsule.

2. The system of claim **1**, wherein the control system is configured automatically identify each location of the one or more targets based on the detection of an edge in the crystalline lens of the patient.

3. The system of claim **1**, wherein the control system is configured to complete the treatment at a location of a first target before moving the focal zone of the laser beam away from the location of the first target.

4. The system of claim **1**, wherein the control system is configured to scan the focal zone of the laser beam from a location of a first target to a second location without completing the treatment at the first location.

5. The system of claim **1**, wherein processing the imaging data comprises displaying the image data to a user and identifying each location of the one or more targets based on user input.

6. The system of claim **1**, wherein the control system is configured to register subsequent images based the one or more targets identified by the user and track the one or more targets.

7. The system of claim **1**, wherein the control system is configured to scan the focal zone of the laser to create one or more fiduciary reference marks in the lens of the patient.

8. The system of claim **1**, wherein the control system is configured to control the laser and the scanning assembly to segment the lens into the discrete fragments by scanning the focal zone in one or more lens fragmentation scanning patterns.

9. The system of claim **8**, wherein the control system is configured to fragment the lens before rupturing the lens capsule.

10. The system of claim **9**, wherein the discrete fragments are sized to be removable through a lumen of an ophthalmic aspiration probe.

11. The system of claim **10**, wherein the controller is further configure to scan the focal zone of the laser beam in the lens capsule to form an incision minimally sized for insertion of the ophthalmic aspiration probe.

12. The system of claim **1**, wherein the the one or more incisions in the lens capsule are bilateral incisions in the lens capsule minimally sized for accommodating at least one selected from the group consisting of an irrigating tip, an aspirating tip, and an ultrasound tip.

13. The system of claim **2**, wherein the controller is further configured to scan the focal zone of the laser beam to form the one or more incisions so as to be minimally sized in the lens capsule for allowing passage of a folding IOL.

* * * * *

EXHIBIT J

US009474648B2

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Palanker et al.

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(45) **Date of Patent: Oct. 25, 2016**

(54) **APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER OPHTHALMIC SURGERY**

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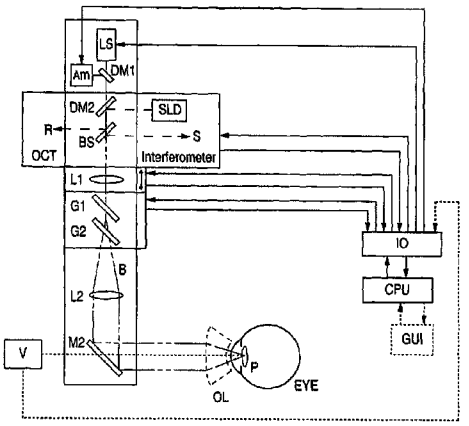
(57) **ABSTRACT**

A system for ophthalmic surgery on an eye includes: a pulsed laser which produces a treatment beam; an OCT imaging assembly capable of creating a continuous depth profile of the eye; an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in one or more floaters in the posterior pole. The system also includes one or more controllers programmed to automatically scan tissues of the patient's eye with the imaging assembly; identify one or more boundaries of the one or more floaters based at least in part on the image data; iii. identify one or more treatment regions based upon the boundaries; and operate the optical scanning system with the pulsed laser to produce a treatment beam directed in a pattern based on the one or more treatment regions.

15 Claims, 10 Drawing Sheets



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13/588,966, filed on Aug. 17, 2012, now Pat. No. 8,709,001, which is a continuation of application No. 11/328,970, filed on Jan. 9, 2006, now Pat. No. 8,394,084.

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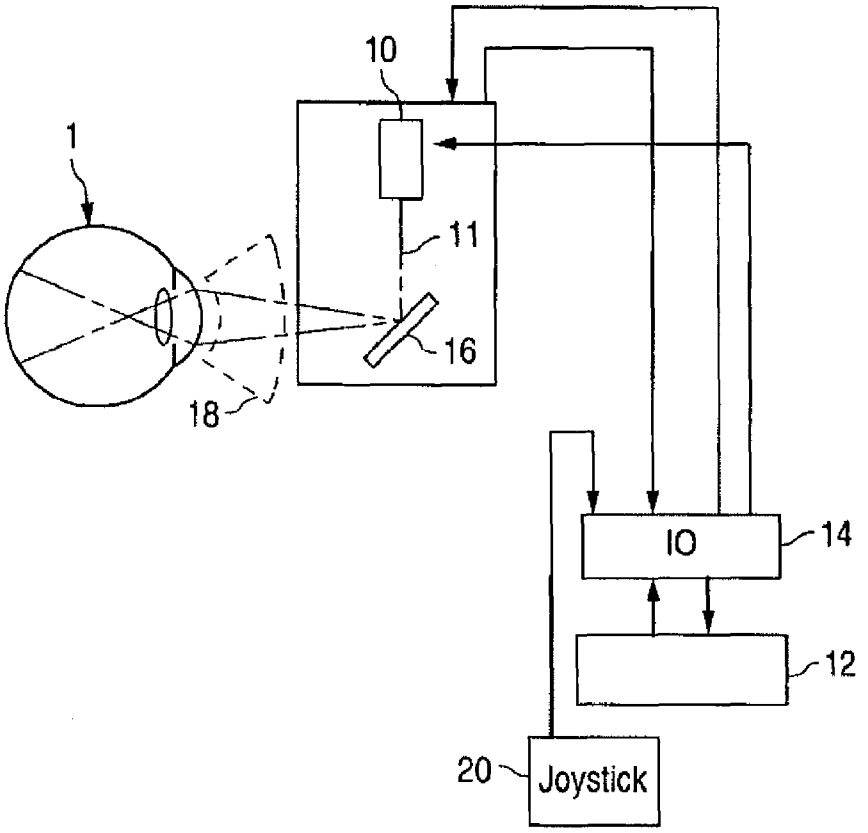

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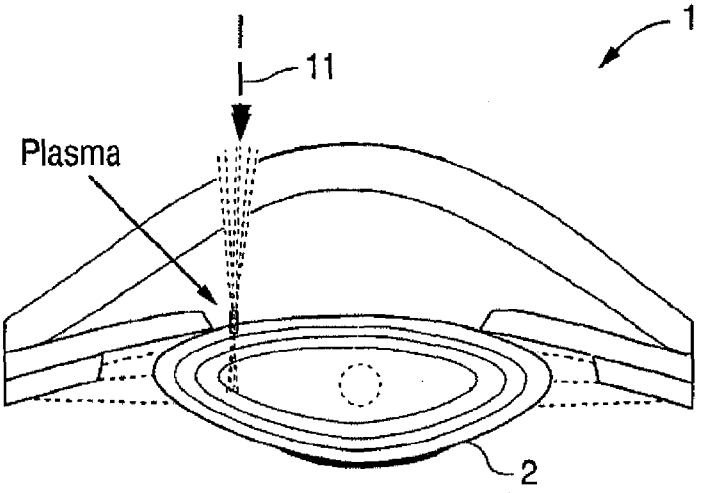

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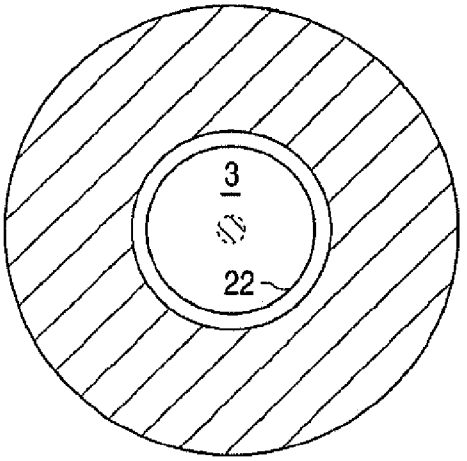

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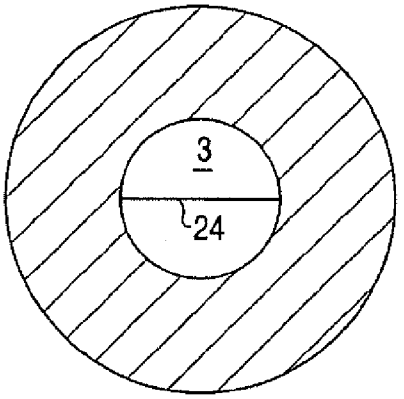

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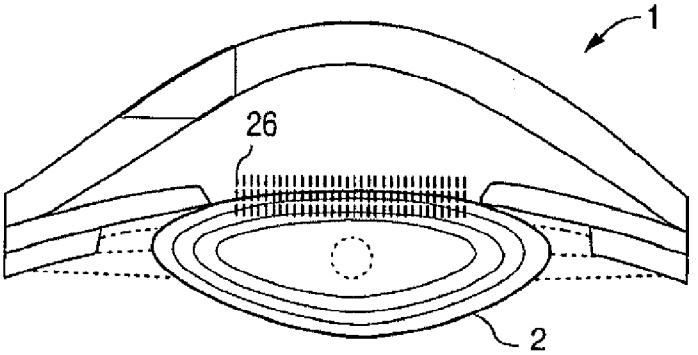

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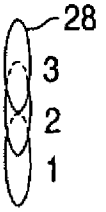

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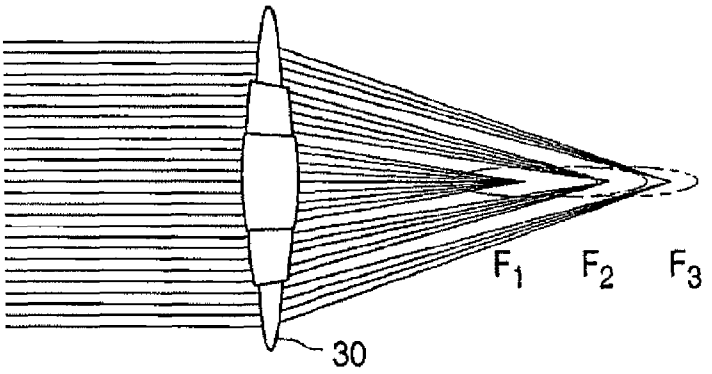


FIG. 7A

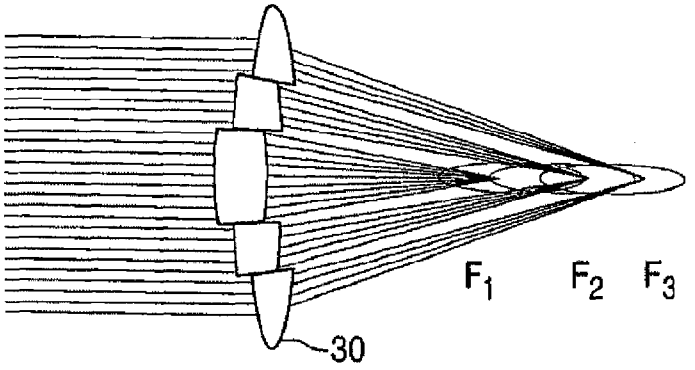


FIG. 7B

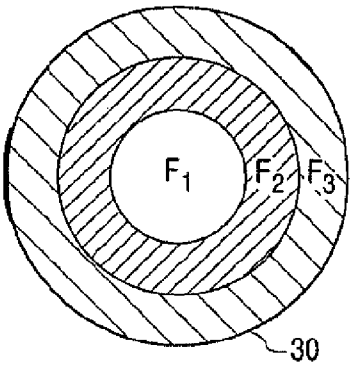


FIG. 7C

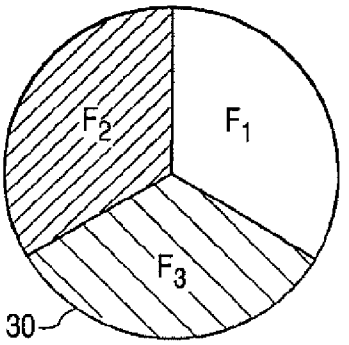
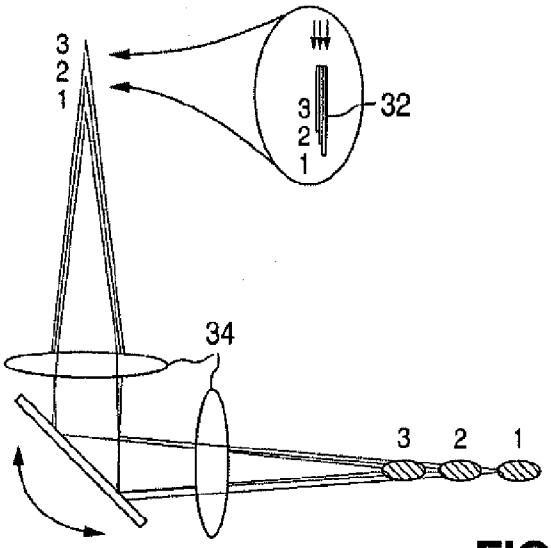


FIG. 7D



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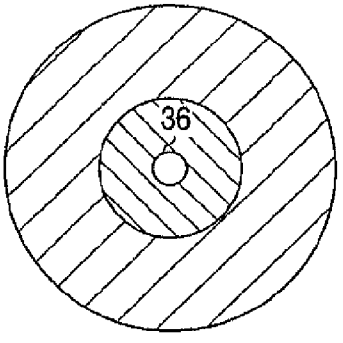


FIG. 9A

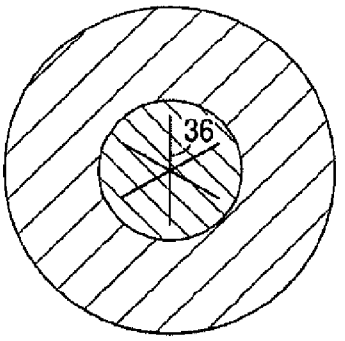


FIG. 9B

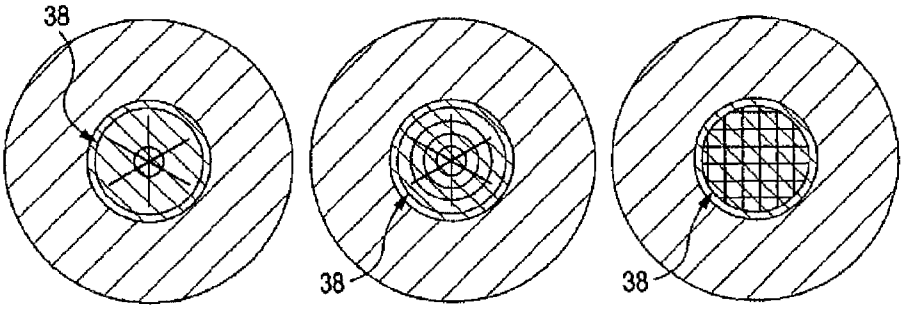


FIG. 10A FIG. 10B FIG. 10C

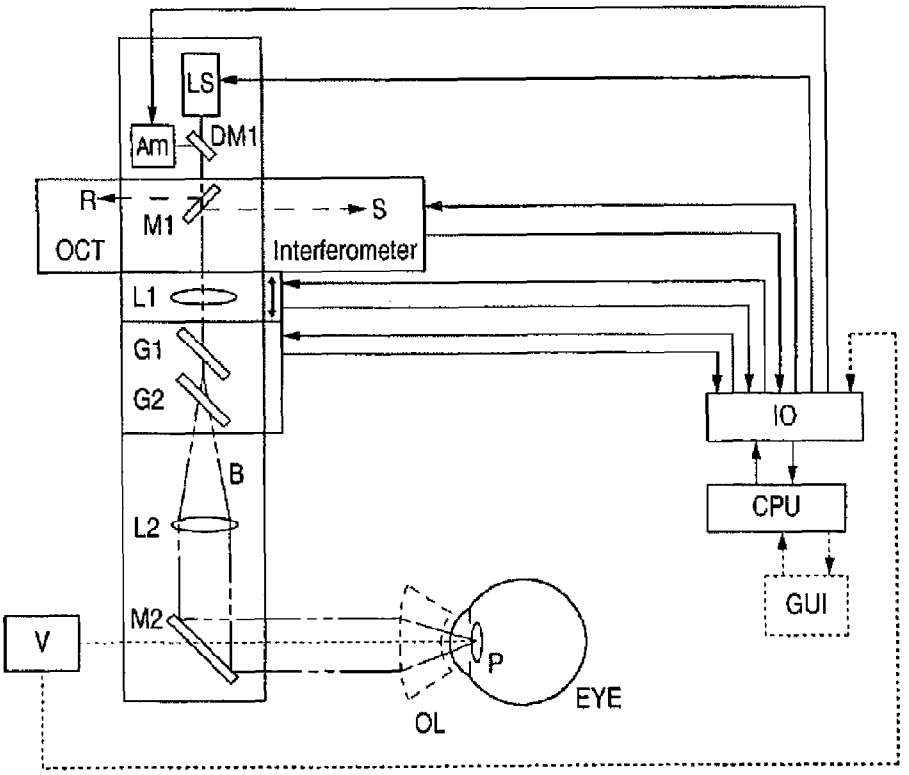
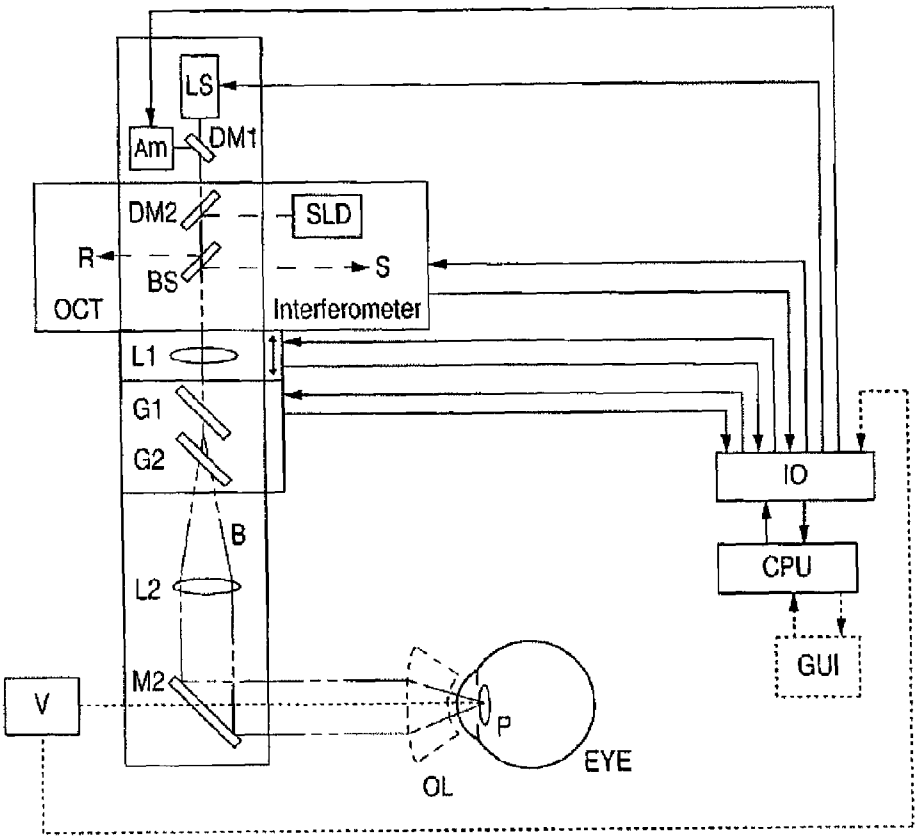


FIG. 11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DM1
DM2
SLD
R
BS
S
OCT
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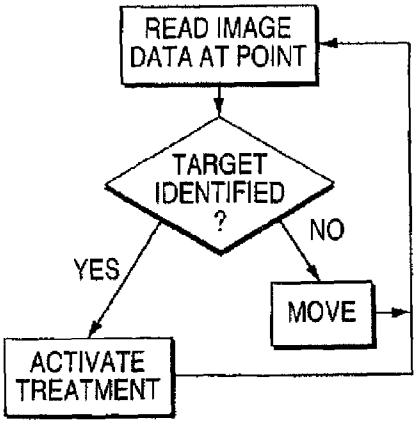
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12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YES
MOVE
ACTIVATE TREATMENT

FIG. 14

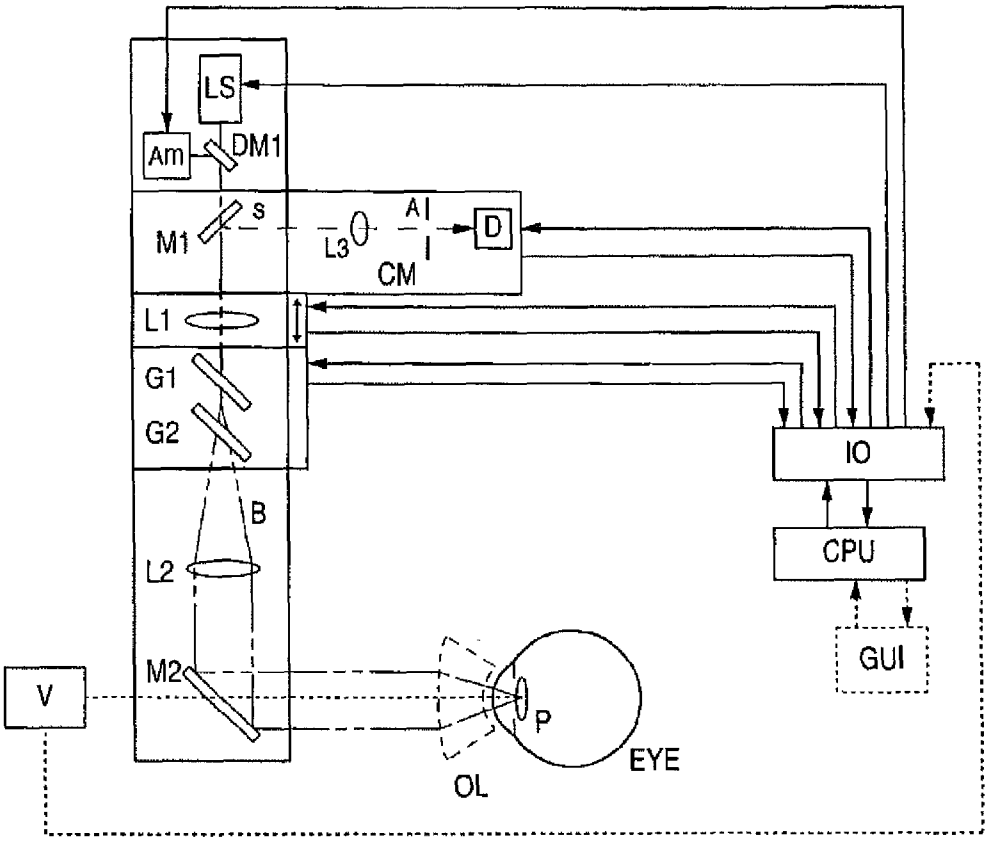


FIG. 13

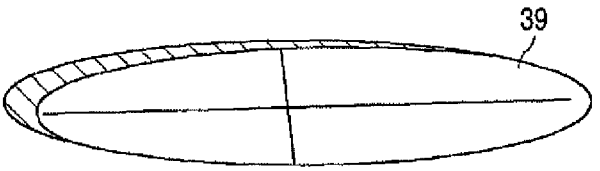


FIG. 16

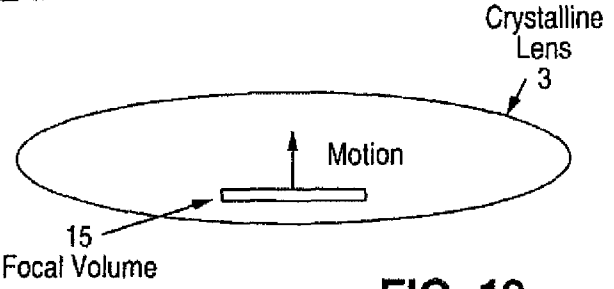
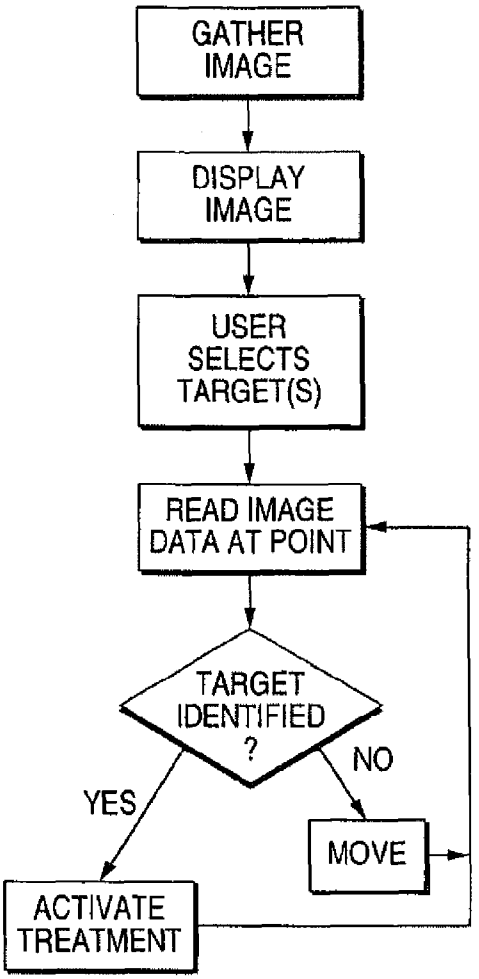


FIG. 19


GATHER IMAGE
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USER SELECTS TARGET(S)
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TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 15

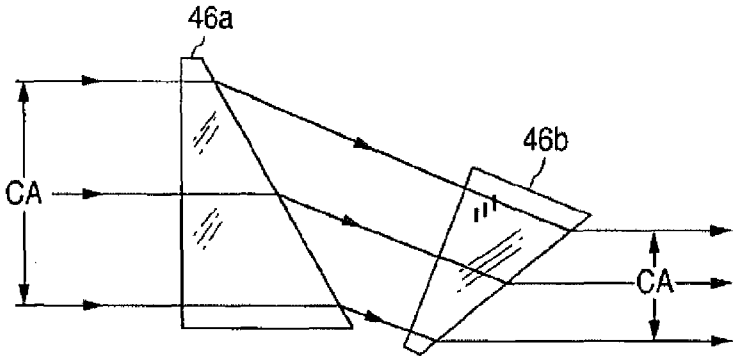
46a
46b
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FIG. 18

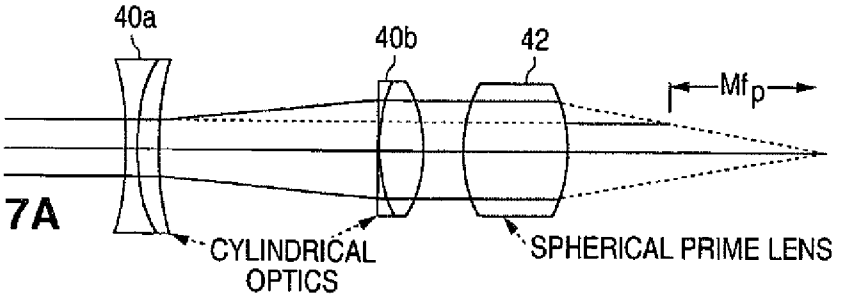

FIG. 17A

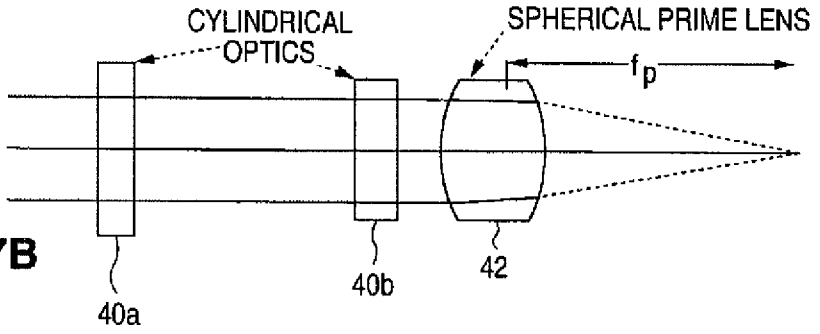

FIG. 17B

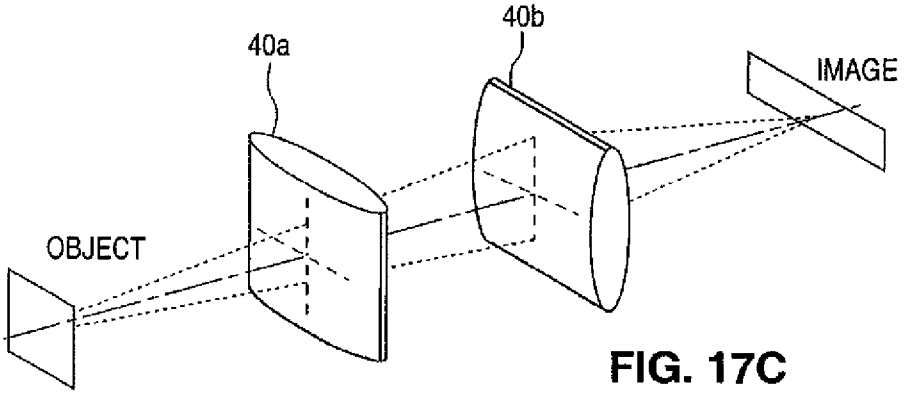

FIG. 17C

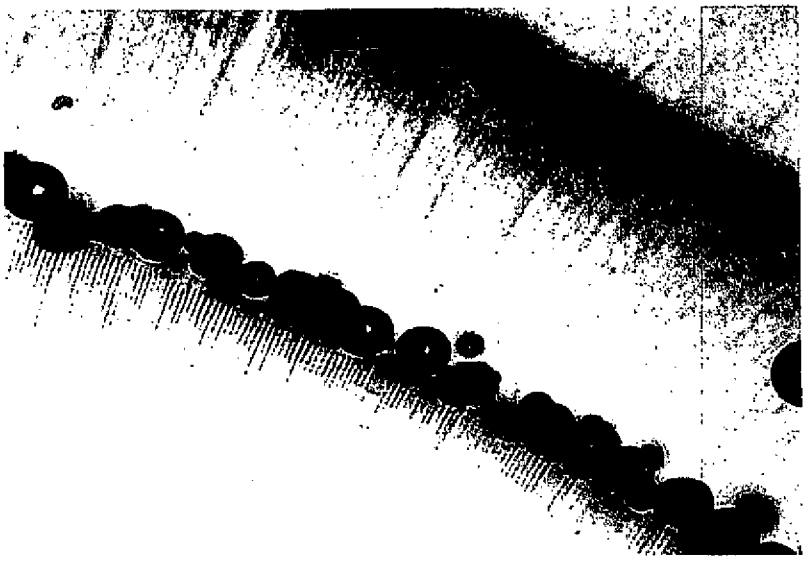

FIG. 20

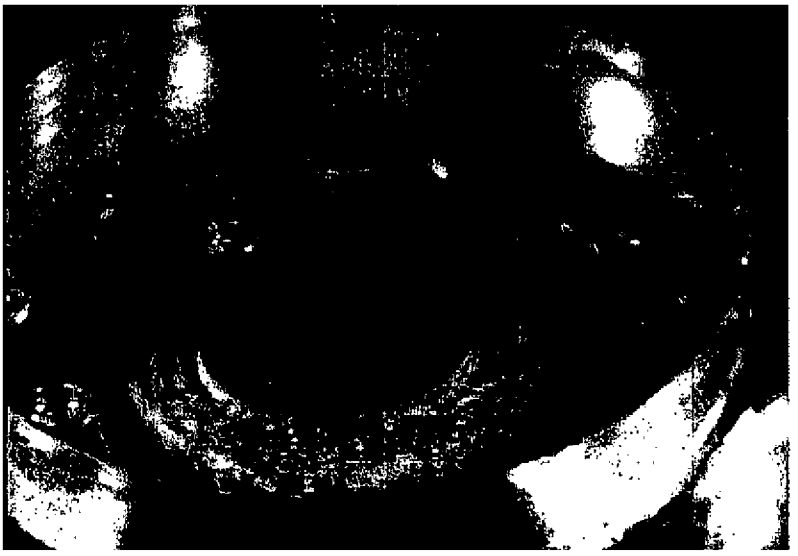

FIG. 21

APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER OPHTHALMIC SURGERY

CROSS-REFERENCE

This application claims priority to and is a continuation of U.S. patent application Ser. No. 14/742,663, filed Jun. 17, 2015, which is a continuation of U.S. patent application Ser. No. 14/184,047, filed Feb. 19, 2014, which is a continuation of U.S. patent application Ser. No. 13/588,966, filed Aug. 17, 2012, which is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It

provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodissection, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation

of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic. foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto

the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**,**2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**,**2**,**3**) focused with a set of lenses into multiple points (**1**,**2**,**3**) and thus producing plasma at different depths inside the tissue (**1**,**2**,**3**).

FIG. **9**A and FIG. **9**B are diagrams illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps
2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.
3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm.

In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda/(2.NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist,

which can be expressed as: $L-\lambda/(4.NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device IO and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmentation zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the

optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal

heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated

herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly;

a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data of at least a portion of the lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data for the patient's crystalline lens;

process the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsule incision scanning pattern to perform the anterior capsule incision, wherein positioning of the focal zone is determined in part by the control system based on the image data.

2. The system of claim **1**, wherein the imaging device comprises an optical coherence tomography (OCT) imaging device.

3. The system of claim **2**, wherein the control system is configured to control the scanning assembly to scan the laser beam relative to the lens to provide the sample input to the OCT imaging device to generate three-dimensional location data for the anterior capsule of the lens of the patient's eye; and the control system is configured to determine the anterior capsulotomy scanning pattern based on the three-dimensional location data for the anterior capsule.

4. The system of claim **1**, wherein the laser beam has a wavelength between 800 nm and 1,100 nm, the laser beam comprises pulses having pulse energy between 1.0 micro joules and 1000 micro joules, a pulse duration between about 100 femtoseconds and about 10 picoseconds, and a pulse repetition rate between 1 kHz and about 100 kHz.

5. The system of claim **1**, wherein the anterior capsule incision scanning pattern is configured to scan the focal zone to different depths, and wherein the focal zone is first scanned at a maximum depth and then scanned to sequentially shallower depths.

6. The system of claim **1**, wherein the control system is configured to control the laser and the scanning assembly to scan the focal zone of the laser beam to segment the lens into the discrete fragments by scanning the focal zone in one or more lens fragmentation scanning patterns.

7. The system of claim **6**, wherein the discrete fragments are sized to be removable through a lumen of an ophthalmic aspiration probe.

8. The system of claim **6**, wherein the one or more lens fragmentation scanning patterns include at least one of a linear pattern, a planar pattern, a radial pattern, a circular pattern, a spiral pattern, a curvilinear pattern, or two or more overlapping line segments.

9. The system of claim **6**, wherein: scanning the focal zone in the one or more lens fragmentation scanning patterns comprises sequentially applying laser pulses to different depths within the lens; and the laser pulses are first applied at a maximum depth within the lens and then applied to sequentially shallower depths within the lens.

10. The system of claim **1**, wherein: the scanning assembly comprises a z-axis scanning device and a transverse scanning device, the z-axis device being operable to change the location of the focal zone of the laser beam parallel to the direction of propagation of the laser beam, the transverse scanning device being operable to scan the location of the focal zone transverse to the direction of propagation of the laser beam; and the scanning assembly is configured such that the laser beam is acted upon by the z-axis scanning device before being acted upon by the transverse scanning device.

11. The system of claim **10**, wherein: the z-axis scanning device comprises one or more movable lenses; and the transverse scanning device comprises one or more controllable scanning elements.

12. The system of claim **1**, wherein the control system is configured to:

process the image data to determine one or more axial locations of the anterior capsule of the lens; and or more anterior capsule axial locations.

13. The system of claim **12**, wherein the control system is configured to determine a posterior cutting boundary for the anterior capsule incision scanning pattern based on the one or more anterior capsule axial locations.

14. The system of claim **1**, wherein the control system is configured to determine an anterior cutting boundary for the anterior capsule incision scanning pattern based on the one or more anterior capsule axial locations.

15. The system of claim **1**, wherein the control system configures the anterior capsule incision scanning pattern based in part on an input from a user interface.

* * * * *

EXHIBIT K

US009693903B2

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Palanker et al.

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(45) **Date of Patent: *Jul. 4, 2017**

(54) **APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER OPHTHALMIC SURGERY**

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This patent is subject to a terminal disclaimer.

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A61F 9/008 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 9/008*** (2013.01); ***A61B 18/20*** (2013.01); ***A61B 90/361*** (2016.02);
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(58) **Field of Classification Search**
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(Continued)

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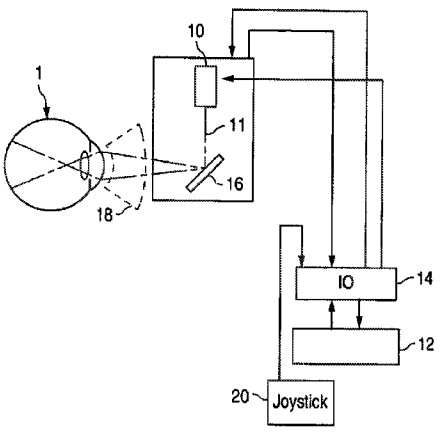
(57) **ABSTRACT**

A system for ophthalmic surgery on an eye includes: a pulsed laser which produces a treatment beam; an OCT imaging assembly capable of creating a continuous depth profile of the eye; an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in one or more floaters in the posterior pole. The system also includes one or more controllers programmed to automatically scan tissues of the patient's eye with the imaging assembly; identify one or more boundaries of the one or more floaters based at least in part on the image data; iii. identify one or more treatment regions based upon the boundaries; and operate the optical scanning system with the pulsed laser to produce a treatment
(Continued)



beam directed in a pattern based on the one or more treatment regions.

18 Claims, 10 Drawing Sheets

Related U.S. Application Data

continuation of application No. 14/742,663, filed on Jun. 17, 2015, now Pat. No. 9,271,870, which is a continuation of application No. 14/184,047, filed on Feb. 19, 2014, now Pat. No. 9,101,448, which is a continuation of application No. 13/558,966, filed on Aug. 17, 2012, now Pat. No. 8,709,001, which is a continuation of application No. 11/328,970, filed on Jan. 9, 2006, now Pat. No. 8,394,084.

(60) Provisional application No. 60/643,056, filed on Jan. 10, 2005.

(51) **Int. Cl.**

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A61F 9/009	(2006.01)
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(58) **Field of Classification Search**

USPC 606/4, 6

See application file for complete search history.

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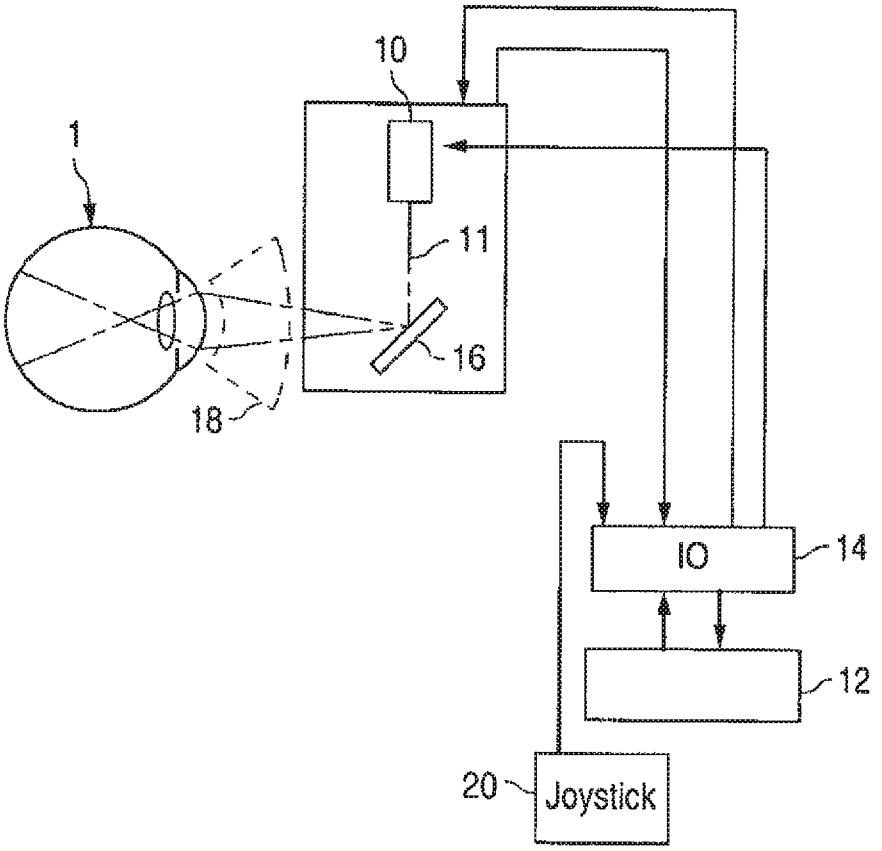

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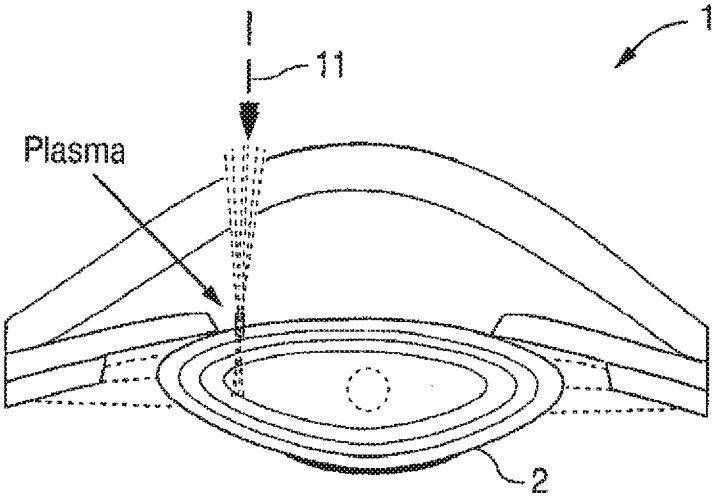

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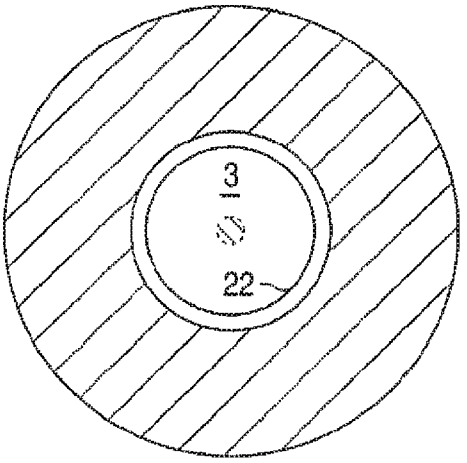

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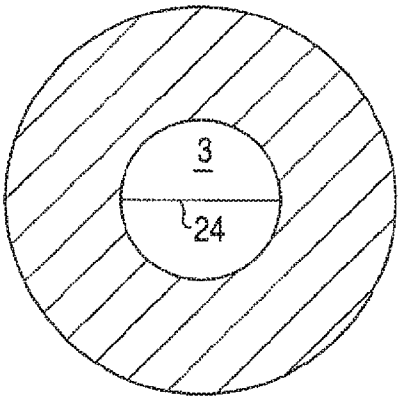


FIG. 4

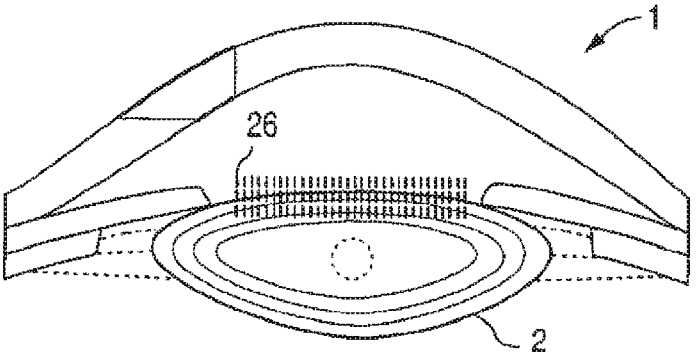
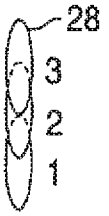


FIG. 5



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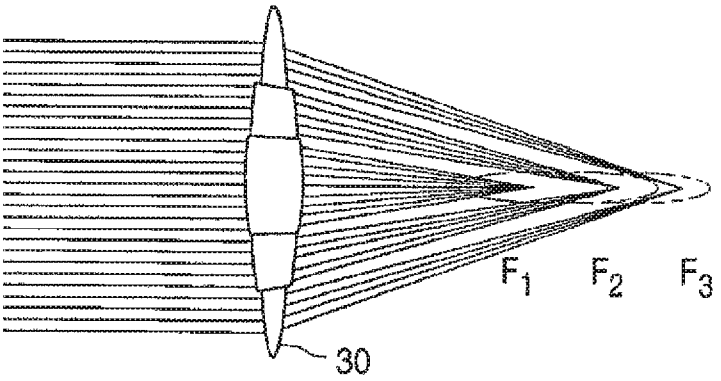

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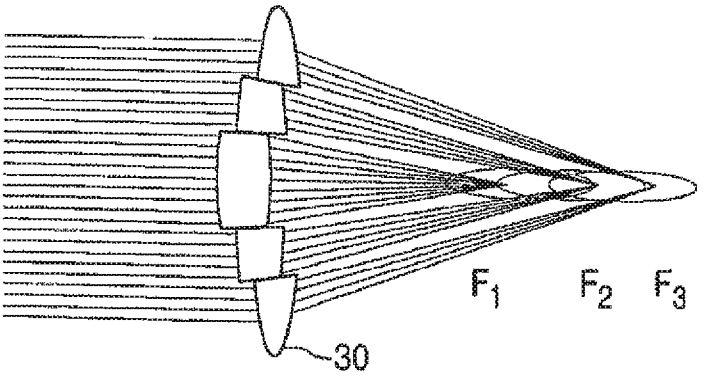

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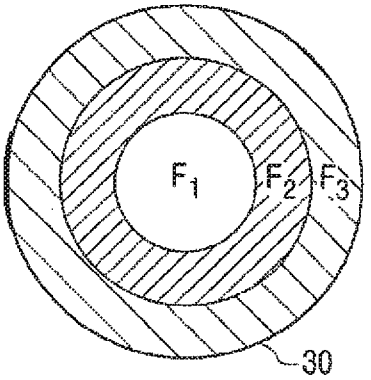


FIG. 7C

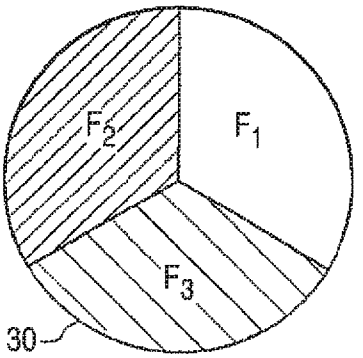
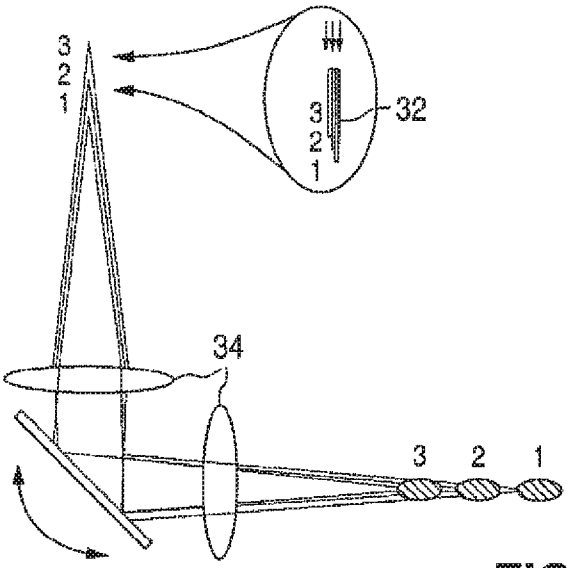


FIG. 7D



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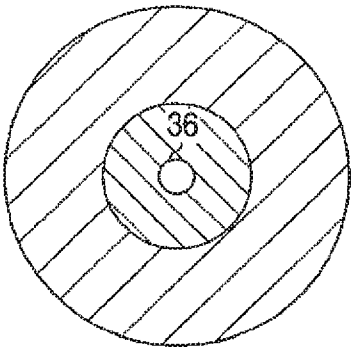


FIG. 9A

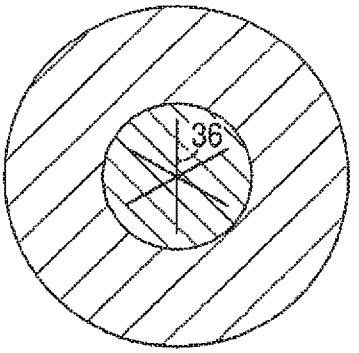


FIG. 9B

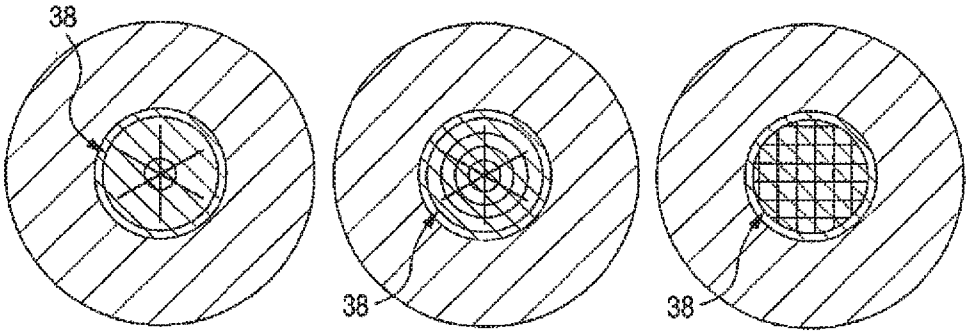
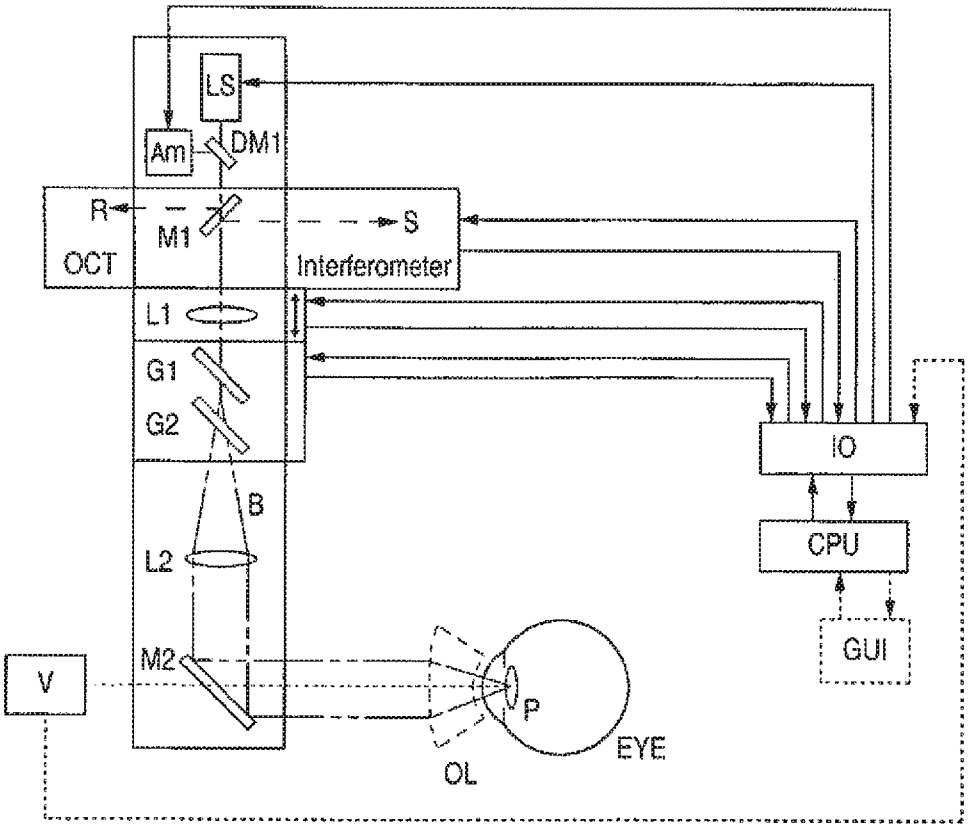


FIG. 10A FIG. 10B FIG. 10C



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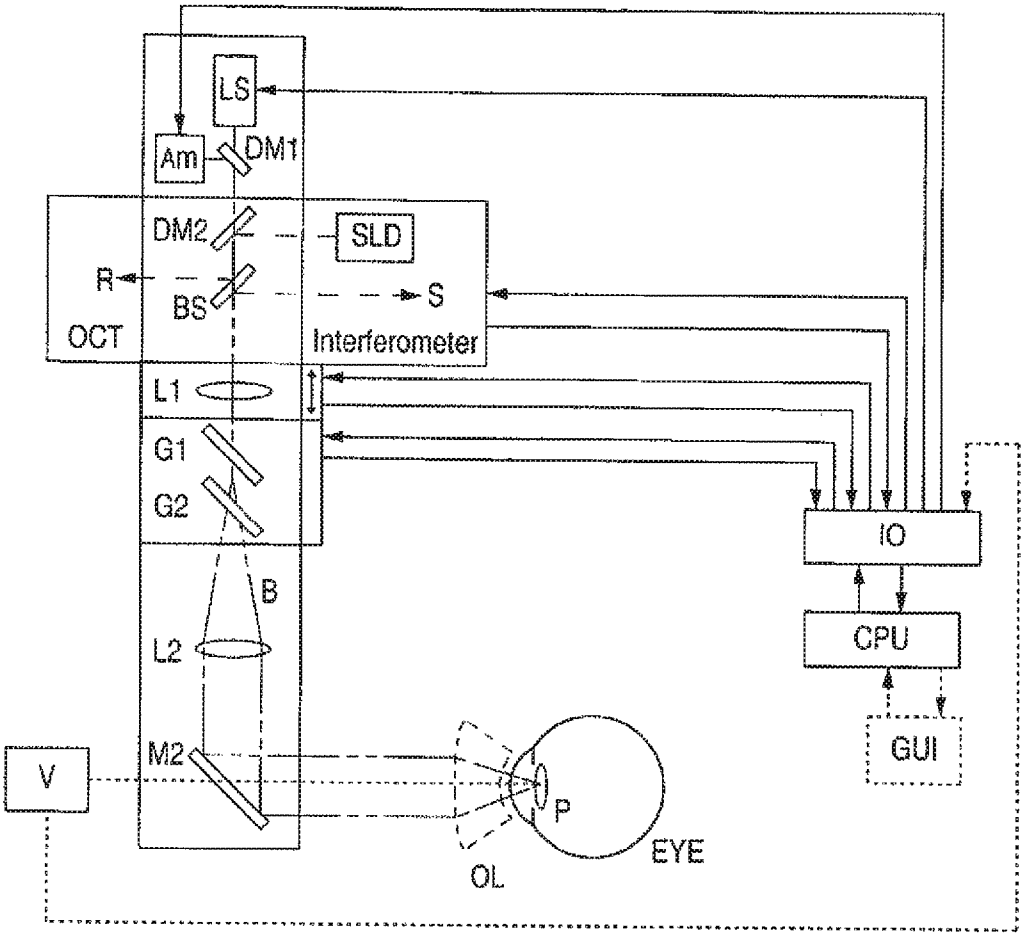
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SLD
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BS
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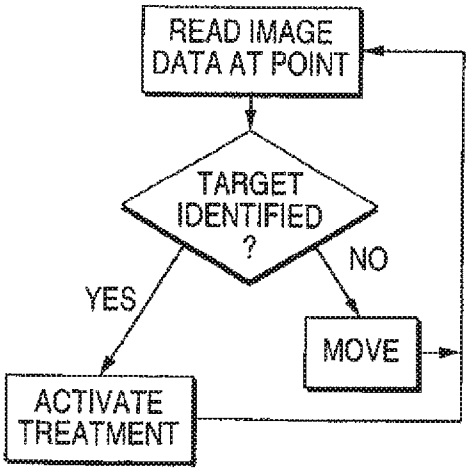
V
P
EYE
OL

FIG. 12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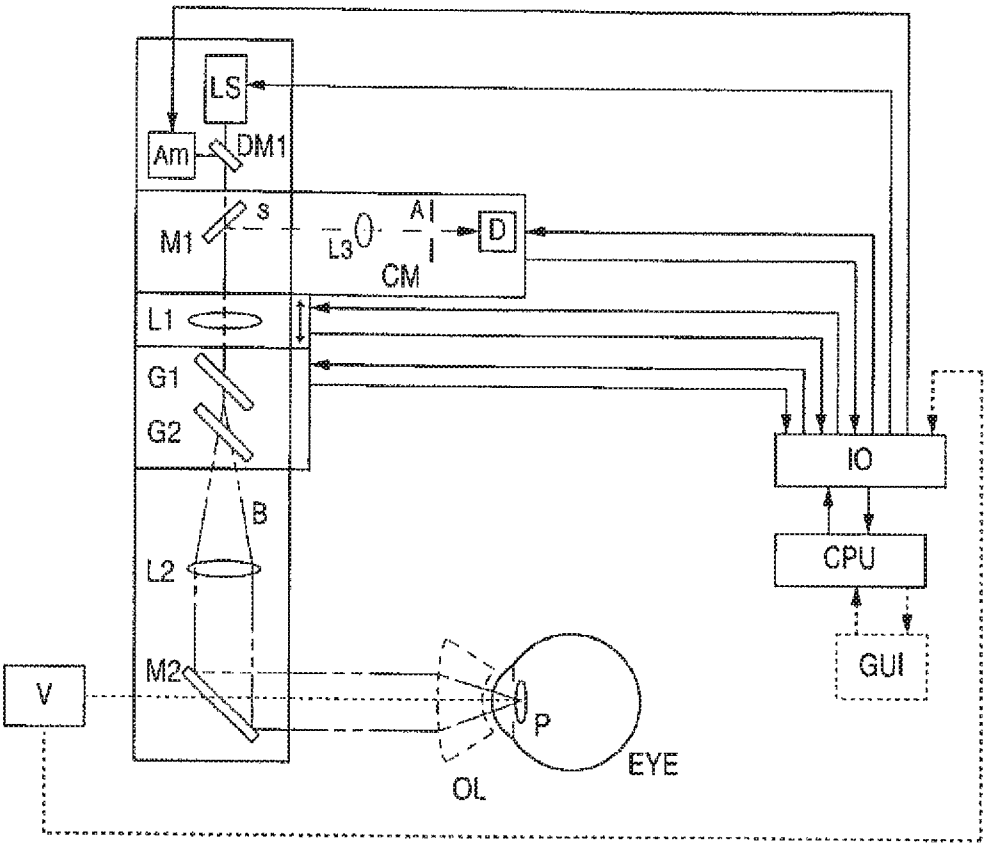
ACTIVATE TREATMENT

FIG. 14



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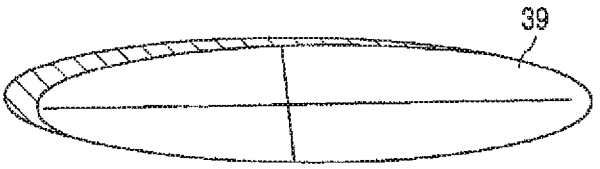


FIG. 16

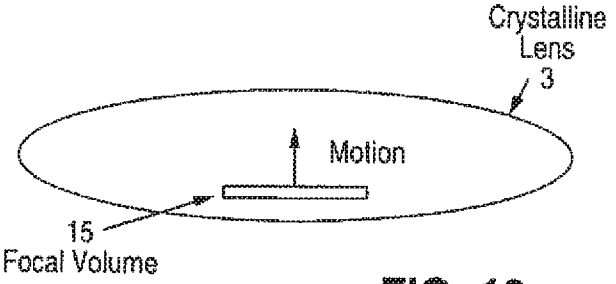
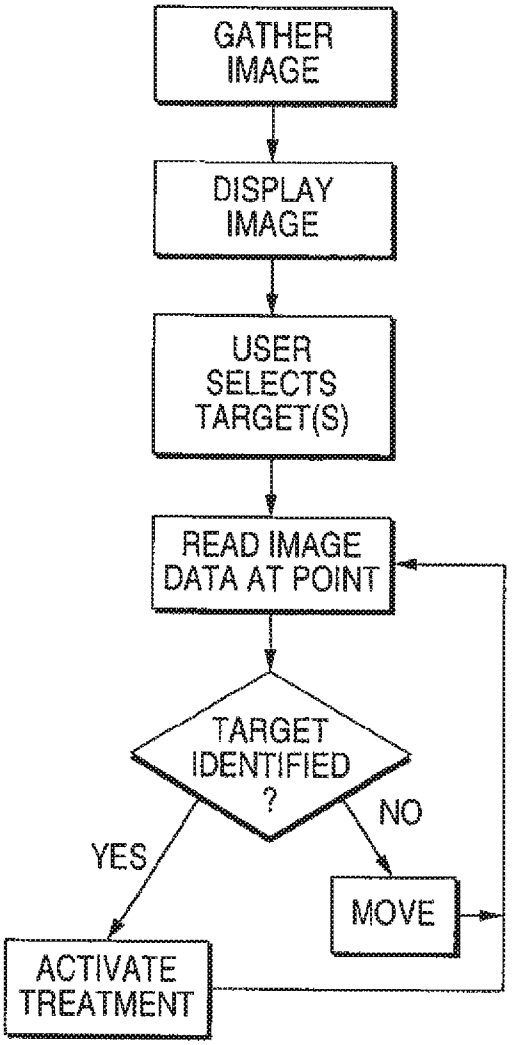


FIG. 19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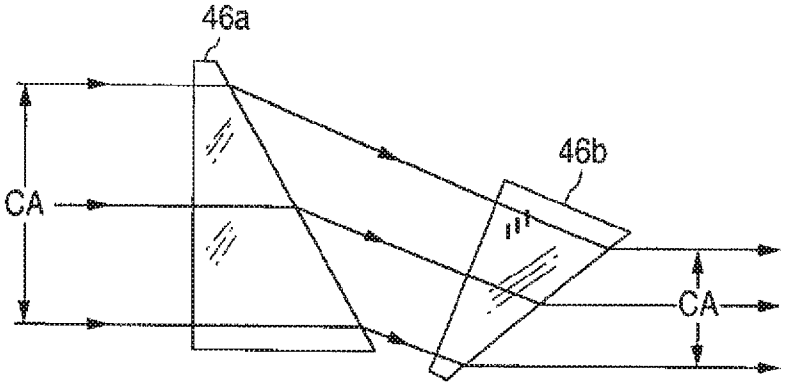
NO
MOVE
ACTIVATE TREATMENT

FIG. 15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46b
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FIG. 18

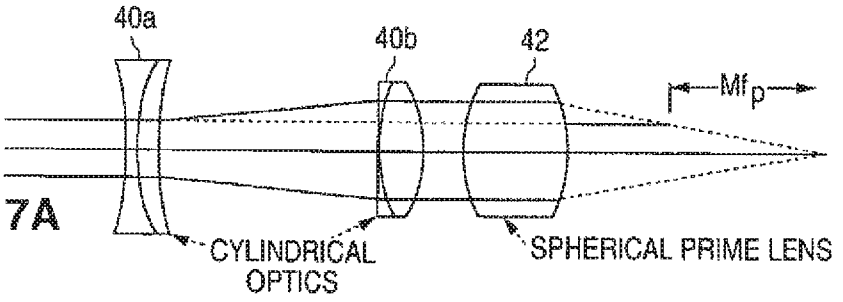

FIG. 17A

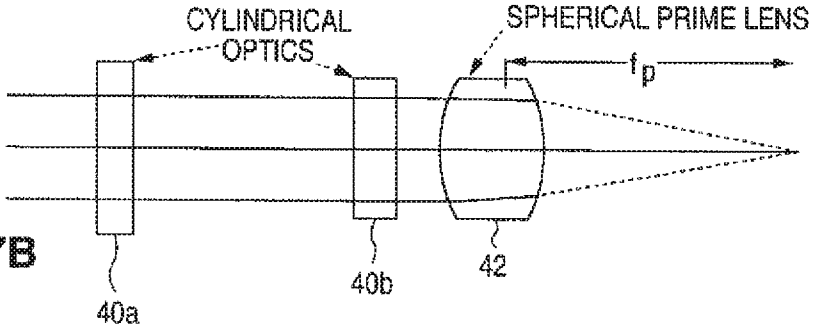

FIG. 17B

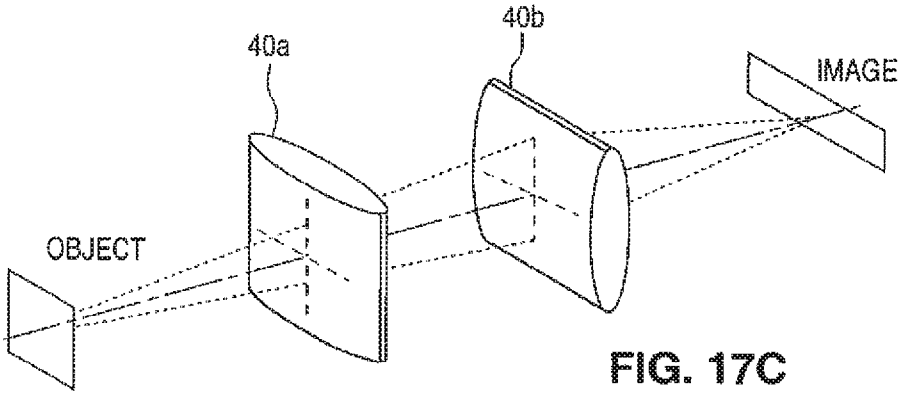

FIG. 17C

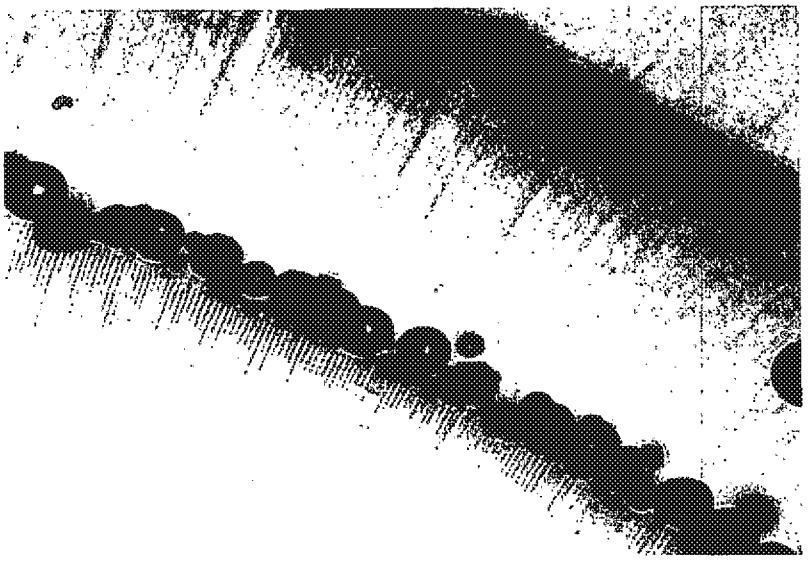

FIG. 20

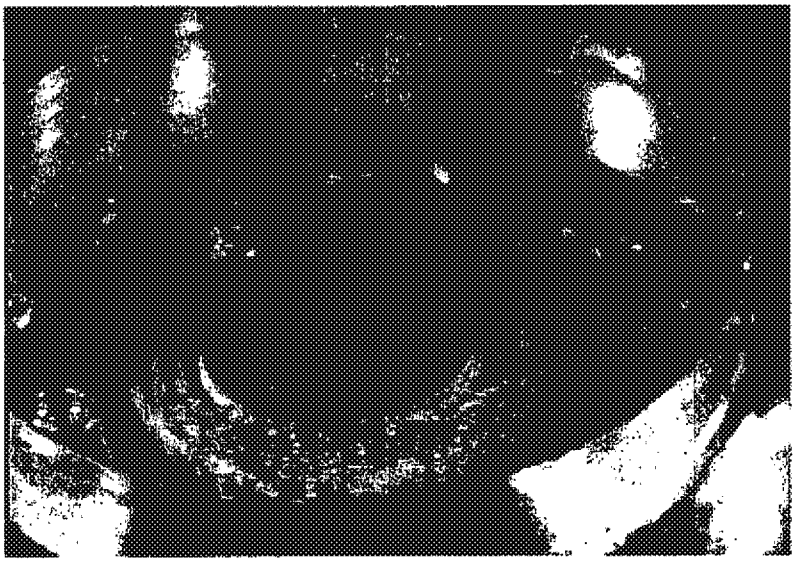

FIG. 21

APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER OPHTHALMIC SURGERY

CROSS-REFERENCE

This application claims priority to and is a continuation of U.S. patent application Ser. No. 14/949,645, filed Nov. 23, 2015, which is a continuation of U.S. patent application Ser. No. 14/742,663, filed Jun. 17, 2015, which is a continuation of U.S. patent application Ser. No. 14/184,047, filed Feb. 19, 2014, which is a continuation of U.S. patent application Ser. No. 13/588,966, filed Aug. 17, 2012, which is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodis section, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be

considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic. foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a

beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**, **2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**, **2**, **3**) focused with a set of lenses into multiple points (**1**, **2**, **3**) and thus producing plasma at different depths inside the tissue (**1**, **2**, **3**).

FIG. **9**A and FIG. **9**B are diagrams illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 μJ, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and λ is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda/(2.NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same

laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L \sim \lambda/(4.NA^2)=dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to

adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device IO and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device IO. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmenta-

tion zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the segmentation component of the procedure duration exceeds

the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that can lead to secondary cataracts. Then, with the lens capsule

intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens;

identify one or more boundaries of the one or more tissue structures of the crystalline lens based at least in part on the image data;

process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries, the lens fragmentation treatment region comprising a posterior cutting boundary located anterior to the posterior capsule of the lens;

process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation pattern comprising a scanning pattern at a plurality of depths within the lens fragmentation treatment region; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the lens fragmentation scanning pattern consecutively at each of the plurality of depths within the lens fragmentation treatment region,

wherein positioning of the focal zone is guided by the control system based on the image data.

2. The system of claim **1**, wherein the imaging device is an optical coherence tomography system.

3. The system of claim **1**, wherein the lens fragmentation treatment region does not transect the posterior capsule.

4. The system of claim **1**, wherein all scanning of the focal zone occurs anterior to the posterior capsule.

5. The system of claim **1**, further comprising a user interface, under operative control of the controller, configure to receive user input comprising one or more parameters used in scanning the eye tissue.

6. The system of claim **1**, wherein the imaging device comprises at least one of a camera, an interferometer, a time domain optical coherence tomography system, a frequency domain optical tomography system, a confocal microscope, and a scanning confocal microscope.

7. The system of claim **6**, wherein the imaging device is a camera.

8. The system of claim **1**, wherein the scanning pattern is selected from the group consisting of: two or more intersecting straight lines, a crosshatched pattern comprising two or more sets of intersecting lines, one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines.

9. The system of claim **1**, wherein the lens is fragmented into segments that can be removed through a lumen of an ophthalmic aspiration probe.

10. A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens;

identify one or more boundaries of the one or more tissue structures of the crystalline lens based at least in part on the image data;

process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in a treatment scanning pattern to effect 3-dimensional patterned laser cutting of the crystalline lens within the lens fragmentation cutting region into a plurality of segments or pieces for subsequent removal,

wherein positioning of the focal zone is guided by the control system based on the image data.

11. The system of claim **10**, wherein the imaging device is an optical coherence tomography system.

12. The system of claim **10**, wherein the lens fragmentation treatment region does not transect the posterior capsule.

13. The system of claim **10**, wherein all scanning of the focal zone occurs anterior to the posterior capsule.

14. The system of claim **10**, further comprising a user interface, under operative control of the controller, configure to receive user input comprising one or more parameters used in scanning the eye tissue.

15. The system of claim **10**, wherein the imaging device comprises at least one of a camera, an interferometer, a time domain optical coherence tomography system, a frequency domain optical tomography system, a confocal microscope, and a scanning confocal microscope.

16. The system of claim **15**, wherein the imaging device is a camera.

17. The system of claim **10**, wherein the scanning pattern is selected from the group consisting of: two or more intersecting straight lines, a crosshatched pattern comprising two or more sets of intersecting lines, one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines.

18. The system of claim **11**, wherein the lens is fragmented into segments that can be removed through a lumen of an ophthalmic aspiration probe.

* * * * *

EXHIBIT L

US009693904B2

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Palanker et al.

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(45) **Date of Patent: *Jul. 4, 2017**

(54) **APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER OPHTHALMIC SURGERY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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A61F 9/008 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 9/008*** (2013.01); ***A61B 18/20*** (2013.01); ***A61B 90/361*** (2016.02);
(Continued)

(58) **Field of Classification Search**
CPC A61F 9/008; A61F 2009/00887
(Continued)

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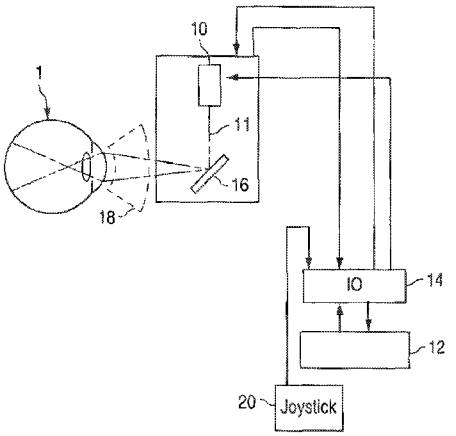
(57) **ABSTRACT**

A system for ophthalmic surgery on an eye includes: a pulsed laser which produces a treatment beam; an OCT imaging assembly capable of creating a continuous depth profile of the eye; an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in one or more floaters in the posterior pole. The system also includes one or more controllers programmed to automatically scan tissues of the patient's eye with the imaging assembly; identify one or more boundaries of the one or more floaters based at least in part on the image data; iii. identify one or more treatment regions based upon the boundaries; and operate the optical scanning system with the pulsed laser to produce a treatment
(Continued)



beam directed in a pattern based on the one or more treatment regions.

20 Claims, 10 Drawing Sheets

Related U.S. Application Data

continuation of application No. 14/742,663, filed on Jun. 17, 2015, now Pat. No. 9,271,870, which is a continuation of application No. 14/184,047, filed on Feb. 19, 2014, now Pat. No. 9,101,448, which is a continuation of application No. 13/588,966, filed on Aug. 17, 2012, now Pat. No. 8,709,001, which is a continuation of application No. 11/328,970, filed on Jan. 9, 2006, now Pat. No. 8,394,084.

(60) Provisional application No. 60/643,056, filed on Jan. 10, 2005.

(51) **Int. Cl.**

A61F 9/007	(2006.01)
A61F 9/009	(2006.01)
A61B 18/20	(2006.01)
A61F 2/16	(2006.01)
A61B 90/00	(2016.01)
A61B 18/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/1602*** (2013.01); ***A61F 9/009*** (2013.01); ***A61F 9/0084*** (2013.01); ***A61F 9/00736*** (2013.01); ***A61F 9/00754*** (2013.01); ***A61F 9/00812*** (2013.01); ***A61F 9/00814*** (2013.01); ***A61F 9/00825*** (2013.01); ***A61F 9/00831*** (2013.01); ***A61F 9/00834*** (2013.01); ***A61F 9/00836*** (2013.01); ***A61F 9/00838*** (2013.01); *A61B 2018/00577* (2013.01); *A61F 2009/0087* (2013.01); *A61F 2009/00844* (2013.01); *A61F 2009/00851* (2013.01); *A61F 2009/00865* (2013.01); *A61F 2009/00878* (2013.01); *A61F 2009/00882* (2013.01); *A61F 2009/00887* (2013.01); *A61F 2009/00889* (2013.01); *A61F 2009/00895* (2013.01); *A61F 2009/00897* (2013.01)

(58) **Field of Classification Search**

USPC 606/4, 6

See application file for complete search history.

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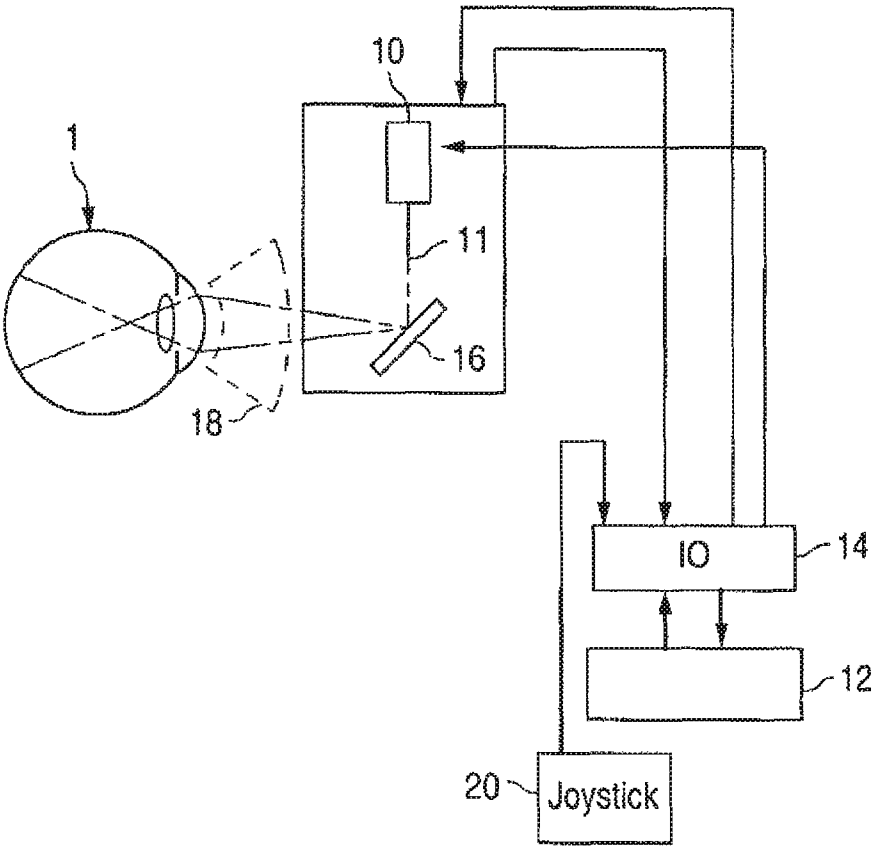

FIG. 1

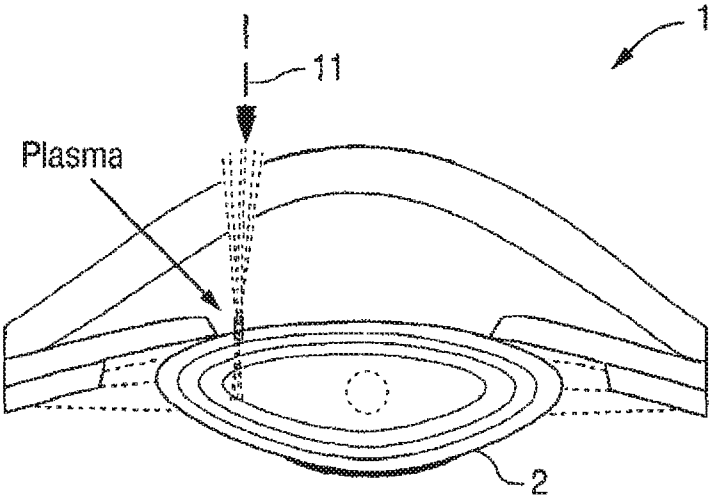

FIG. 2

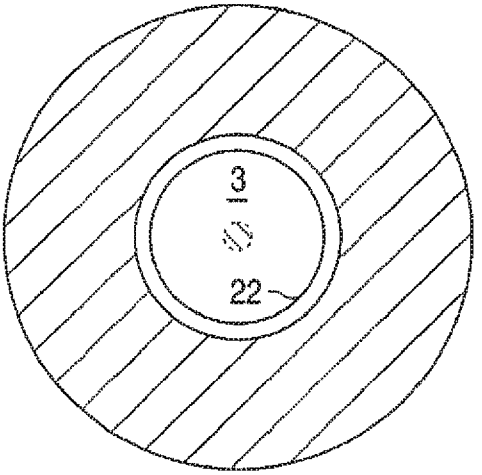

FIG. 3

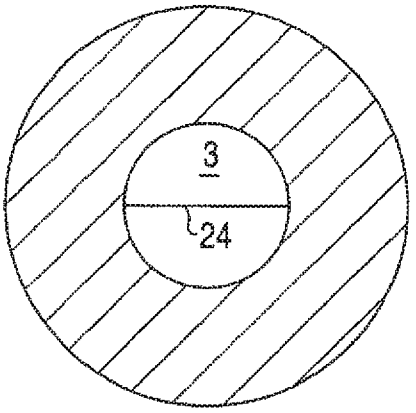

FIG. 4

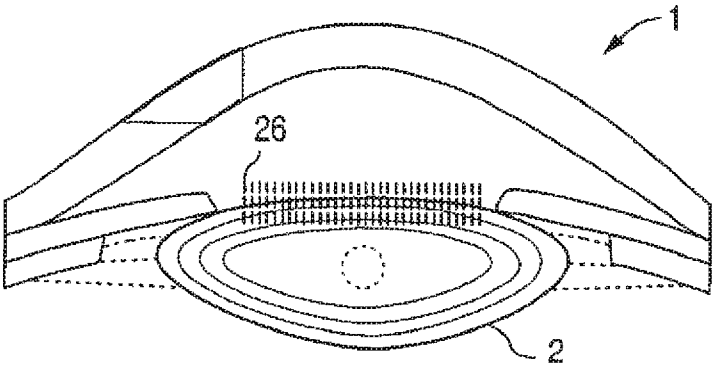

FIG. 5

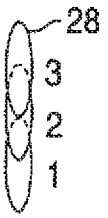

FIG. 6

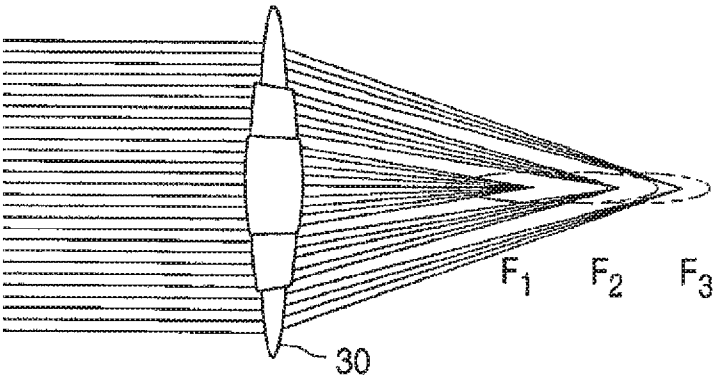

FIG. 7A

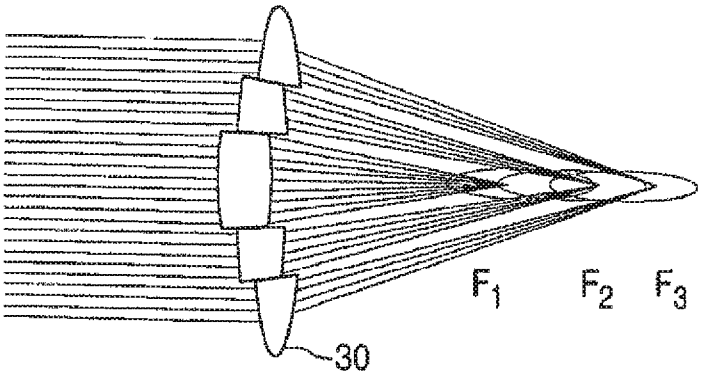

FIG. 7B

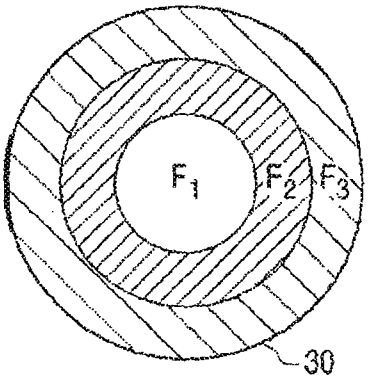

FIG. 7C

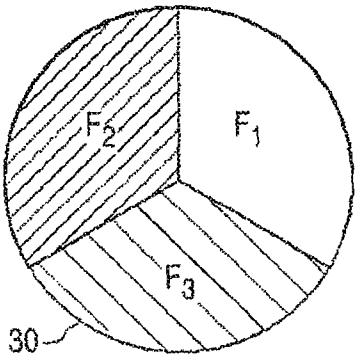

FIG. 7D

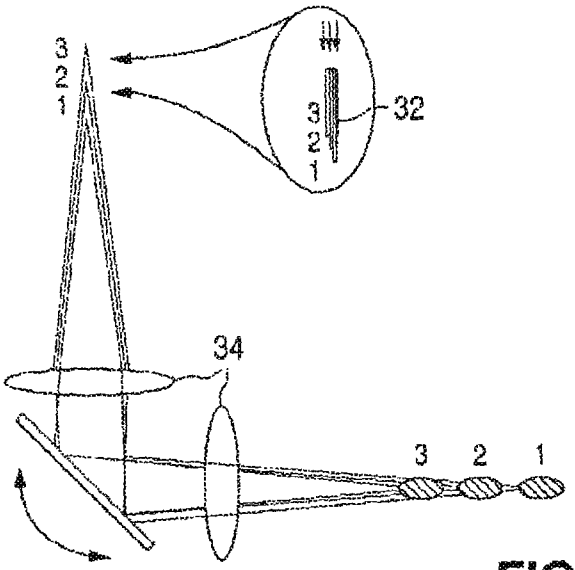

FIG. 8

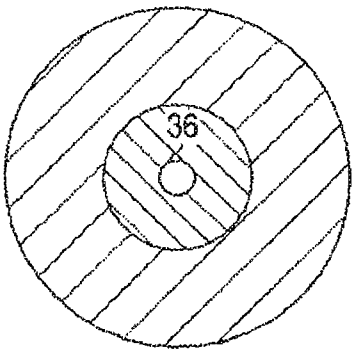

FIG. 9A

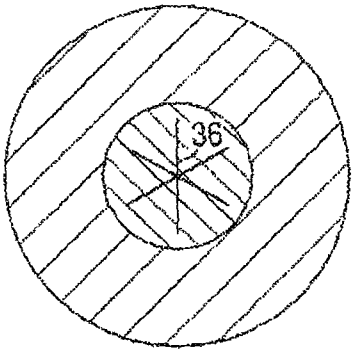

FIG. 9B

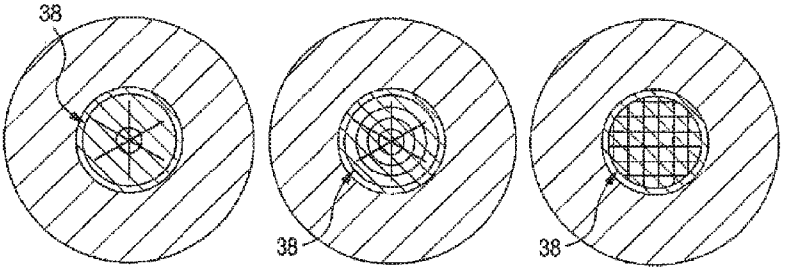

FIG. 10A FIG. 10B FIG. 10C

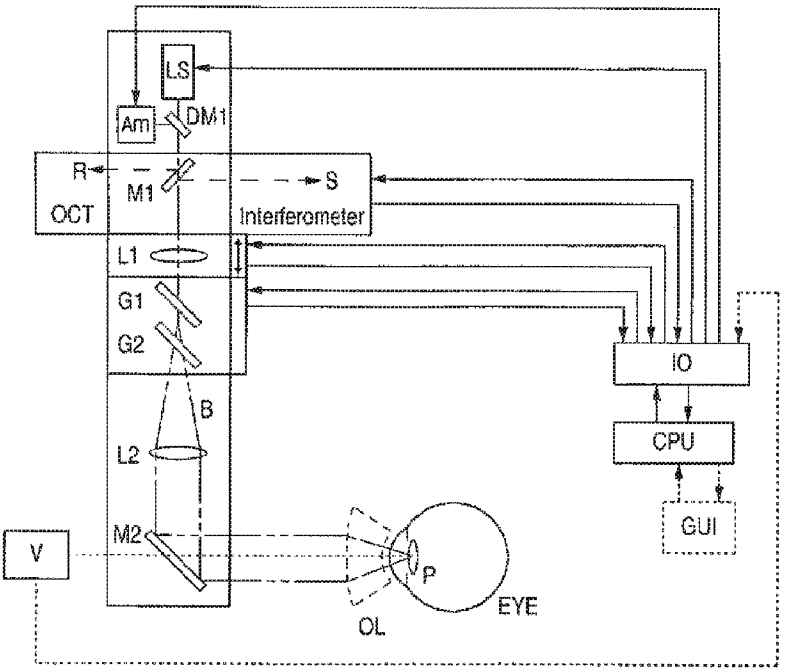

FIG. 11

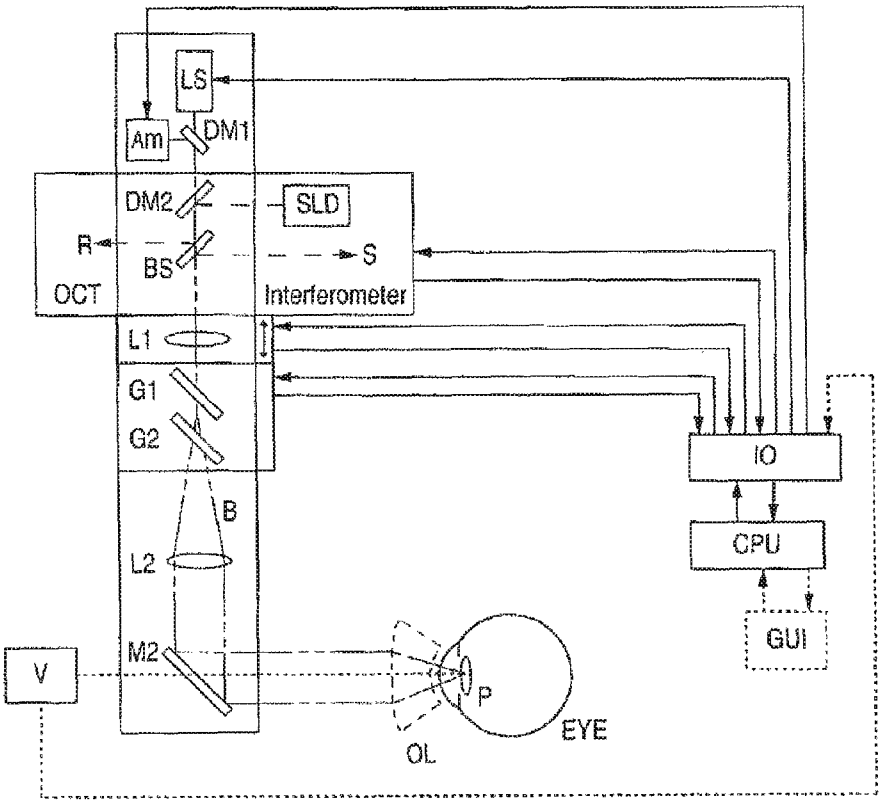
LS
Am
DM1
DM2
SLD
R
BS
S
OCT
Interferometer
L1
G1
G2
IO
B
CPU
L2
GUI
M2
V
P
EYE
OL

FIG. 12

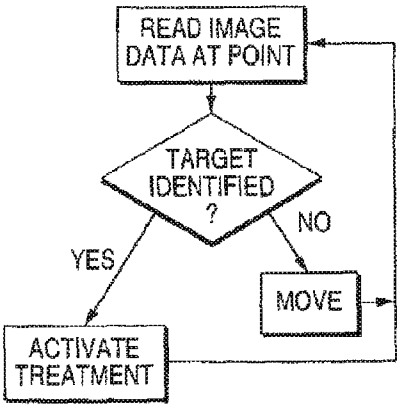
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
NO
YES
MOVE
ACTIVATE TREATMENT

FIG. 14

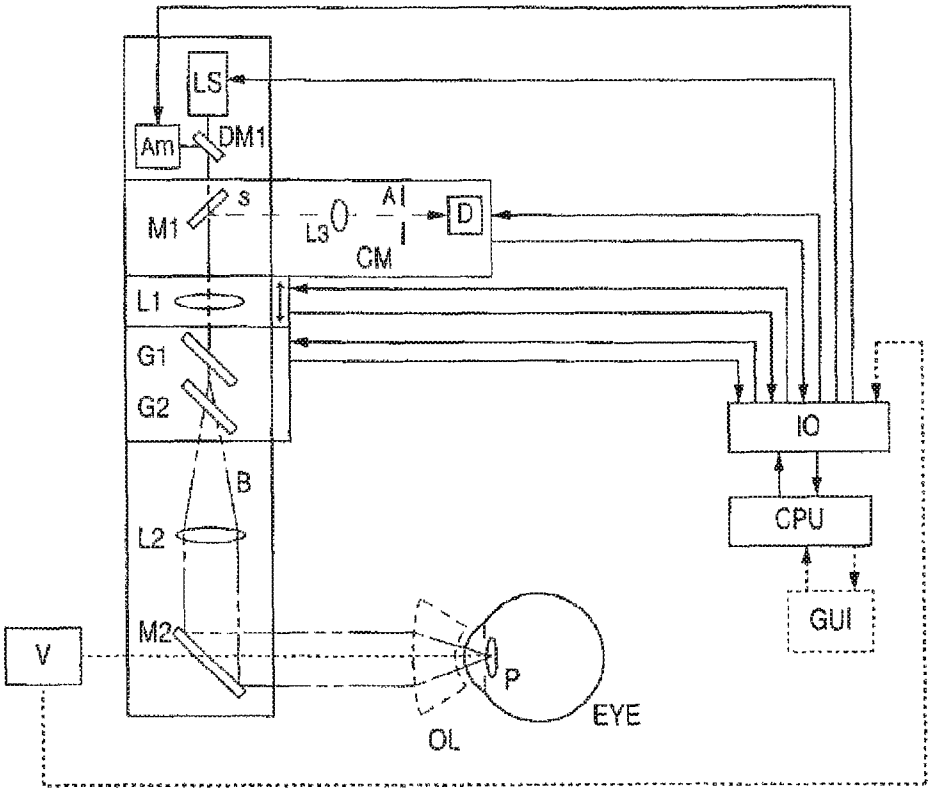

FIG. 13

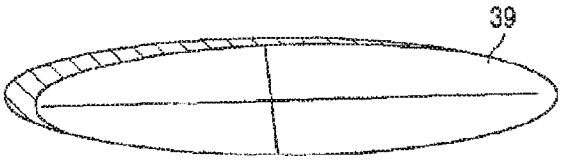

FIG. 16

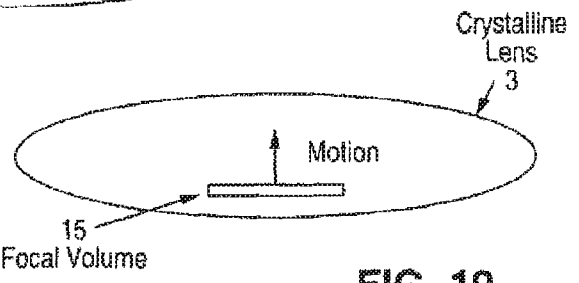

FIG. 19

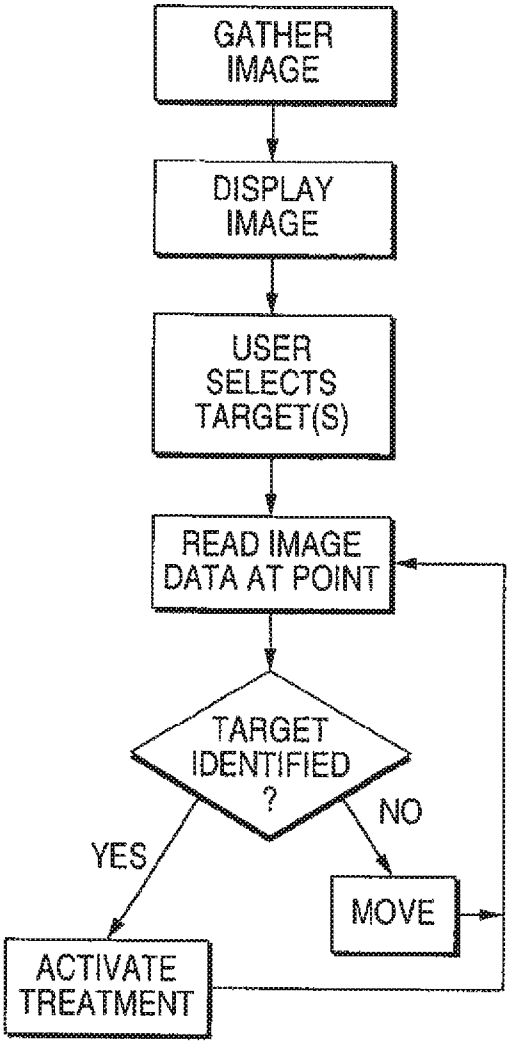
GATHER IMAGE
DISPLAY IMAGE
USER SELECTS TARGET(S)
READ IMAGE DATA AT POINT
TARGET IDENTIFIED ?
YES
NO
MOVE
ACTIVATE TREATMENT

FIG. 15

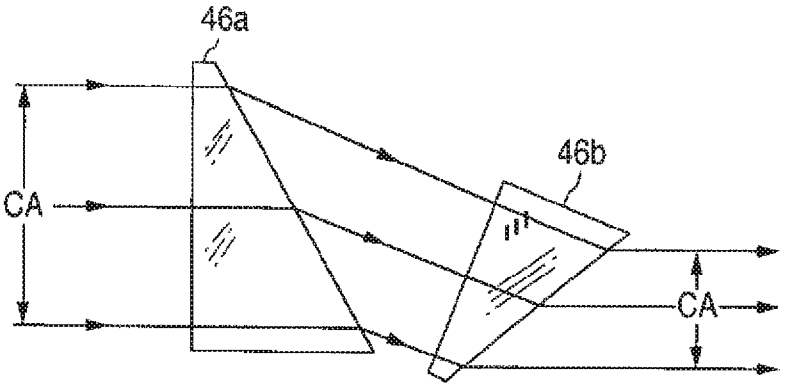
46a
46b
CA
CA

FIG. 18

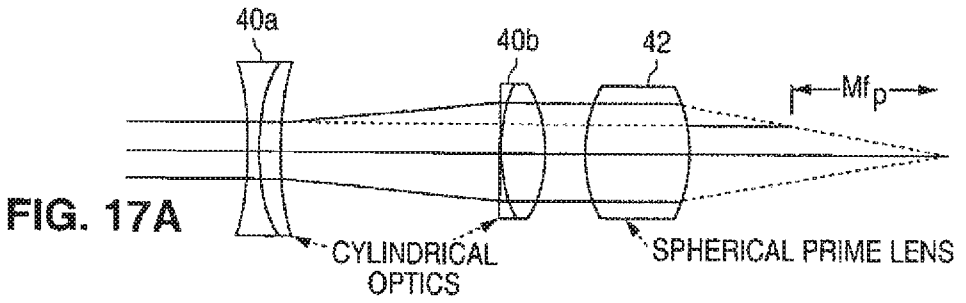

FIG. 17A

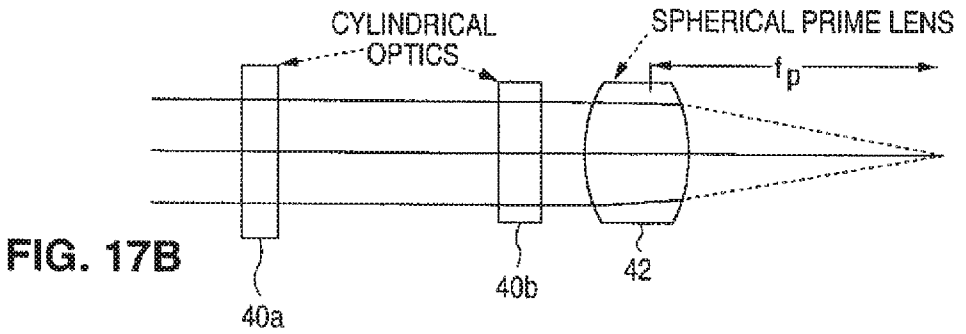

FIG. 17B

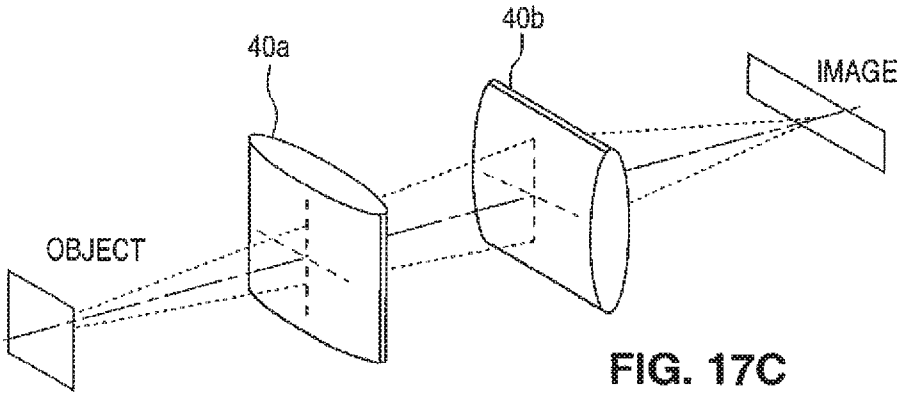

FIG. 17C

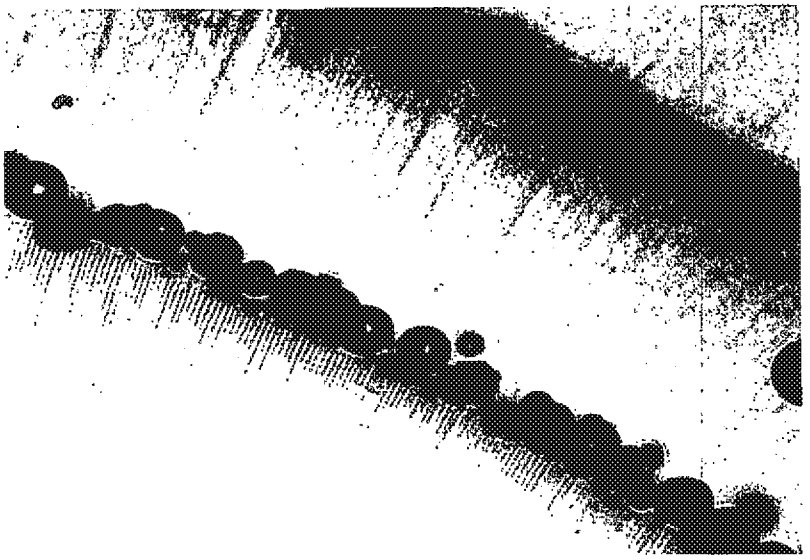

FIG. 20

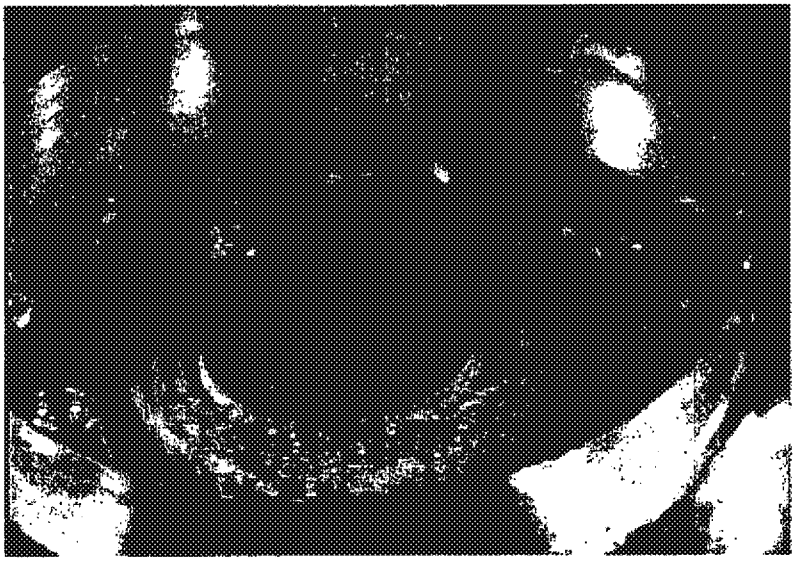

FIG. 21

APPARATUS FOR PATTERNED PLASMA-MEDIATED LASER OPHTHALMIC SURGERY

CROSS-REFERENCE

This application claims priority to and is a continuation of U.S. patent application Ser. No. 14/949,675, filed Nov. 23, 2015, which is a continuation of U.S. patent application Ser. No. 14/742,663, filed Jun. 17, 2015, which is a continuation of U.S. patent application Ser. No. 14/184,047, filed Feb. 19, 2014, which is a continuation of U.S. patent application Ser. No. 13/588,966, filed Aug. 17, 2012, which is a continuation of U.S. patent application Ser. No. 11/328,970, filed Jan. 9, 2006, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/643,056, filed Jan. 10, 2005, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimates of 2.5 million cases being performed annually in the United States and 9.1 million cases worldwide. This is expected to increase to approximately 13.3 million cases by 2006 globally. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modern cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOL's) inserted into the eye through a small incision. This technique is associated with a very high rate of anatomic and visual success exceeding 95% in most cases and with rapid visual rehabilitation.

One of the earliest and most critical steps in the procedure is the performance of capsulorhexis. This step evolved from an earlier technique termed can-opener capsulotomy in which a sharp needle was used to perforate the anterior lens capsule in a circular fashion followed by the removal of a circular fragment of lens capsule typically in the range of 5-8 mm in diameter. This facilitated the next step of nuclear sculpting by phacoemulsification. Due to a variety of complications associated with the initial can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. These were pioneered by Neuhann, and Gimbel and highlighted in a publication in 1991 (Gimbel, Neuhann, Development Advantages and Methods of the Continuous Curvilinear Capsulorhexis. *Journal of Cataract and Refractive Surgery* 1991; 17:110-111, incorporated herein by reference). The concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

Using the older technique of can-opener capsulotomy, or even with the continuous capsulorhexis, problems may develop related to inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity. Some of the problems with visualization have been minimized through the use of dyes such as methylene blue or indocyanine green. Additional complications arise in patients with weak zonules (typically older patients) and very young children that have very soft and elastic capsules, which are very difficult to mechanically rupture.

Finally, during the intraoperative surgical procedure, and subsequent to the step of anterior continuous curvilinear capsulorhexis, which typically ranges from 5-7 mm in diameter, and prior to IOL insertion the steps of hydrodis section, hydrodilineation and phaco emulsification occur. These are intended to identify and soften the nucleus for the purposes of removal from the eye. These are the longest and thought to be the most dangerous step in the procedure due to the use of pulses of ultrasound that may lead to inadvertent ruptures of the posterior lens capsule, posterior dislocation of lens fragments, and potential damage anteriorly to the corneal endothelium and/or iris and other delicate intraocular structures. The central nucleus of the lens, which undergoes the most opacification and thereby the most visual impairment, is structurally the hardest and requires special techniques. A variety of surgical maneuvers employing ultrasonic fragmentation and also requiring considerable technical dexterity on the part of the surgeon have evolved, including sculpting of the lens, the so-called "divide and conquer technique" and a whole host of similarly creatively named techniques, such as phaco chop, etc. These are all subject to the usual complications associated with delicate intraocular maneuvers (Gimbel. Chapter 15: Principles of Nuclear PhacoEmulsification. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: 153-181, incorporated herein by reference.).

Following cataract surgery one of the principal sources of visual morbidity is the slow development of opacities in the posterior lens capsule, which is generally left intact during cataract surgery as a method of support for the lens, to provide good centration of the IOL, and also as a means of preventing subluxation posteriorly into the vitreous cavity. It has been estimated that the complication of posterior lens capsule opacification occurs in approximately 28-50% of patients (Steinert and Richter. Chapter 44. *In Cataract Surgery Techniques Complications and Management.* 2nd ed. Edited by Steinert et al. 2004: pg. 531-544 and incorporated herein by reference). As a result of this problem, which is thought to occur as a result of epithelial and fibrous metaplasia along the posterior lens capsule centrally from small islands of residual epithelial cells left in place near the equator of the lens, techniques have been developed initially using surgical dissection, and more recently the neodymium YAG laser to make openings centrally in a non-invasive fashion. However, most of these techniques can still be

considered relatively primitive requiring a high degree of manual dexterity on the part of the surgeon and the creation of a series of high energy pulses in the range of 1 to 10 mJ manually marked out on the posterior lens capsule, taking great pains to avoid damage to the intraocular lens. The course nature of the resulting opening is illustrated clearly in FIG. 44-10, pg. 537 of Steinert and Richter, Chapter 44 of *In Cataract Surgery Techniques Complications and Management.* 2nd ed (see complete cite above).

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

The techniques and system disclosed herein provide many advantages. Specifically, rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting. The duration of the procedure and the risk associated with opening the capsule and fragmentation of the hard nucleus are reduce, while increasing precision of the procedure. The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle. The removal of a lens dissected into small segments is performed using patterned laser scanning and using a ultrasonic emulsifier with a conventional phacoemulsification technique or a technique modified to recognize that a segmented lens will likely be more easily removed (i.e., requiring less surgical precision or dexterity) and/or at least with marked reduction in ultrasonic emulsification power, precision and/or duration. There are surgical approaches that enable the formation of very small and geometrically precise opening(s) in precise locations on the lens capsule, where the openings in the lens capsule would be very difficult if not impossible to form using conventional, purely manual techniques. The openings enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. For example, the techniques described herein may be used to facilitate anterior and/or posterior lens removal, implantation of injectable or small foldable IOLs as well as injection of compounds or structures suited to the formation of accommodating IOLs.

Another procedure enabled by the techniques described herein provides for the controlled formation of a hemi-circular or curvilinear flap in the anterior lens surface. Contrast to conventional procedures which require a complete circle or nearly complete circular cut. Openings formed using conventional, manual capsulorhexis techniques rely primarily on the mechanical shearing properties of lens capsule tissue and uncontrollable tears of the lens capsule to form openings. These conventional techniques are confined to the central lens portion or to areas accessible using mechanical cutting instruments and to varying limited degrees utilize precise anatomical measurements during the formation of the tears. In contrast, the controllable, patterned laser techniques described herein may be used to create a semi-circular capsular flap in virtually any position on the anterior lens surface and in virtually any shape. They may be able to seal spontaneously or with an autologous or synthetic tissue glue or other method. Moreover, the controllable, patterned laser techniques described herein also have available and/or utilize precise lens capsule size, measurement and other dimensional information that allows the flap or opening formation while minimizing impact on surrounding tissue. The flap is not limited only to semi-circular but may be any shape that is conducive to follow on procedures such as, for example, injection or formation of complex or advanced IOL devices or so called injectable polymeric or fixed accommodating IOLs.

The techniques disclosed herein may be used during cataract surgery to remove all or a part of the anterior capsule, and may be used in situations where the posterior capsule may need to be removed intraoperatively, for example, in special circumstances such as in children, or when there is a dense posterior capsular opacity which can not be removed by suction after the nucleus has been removed. In the first, second and third years after cataract surgery, secondary opacification of the posterior lens capsule is common and is benefited by a posterior capsulotomy which may be performed or improved utilizing aspects of the techniques disclosed herein.

Because of the precision and atraumatic nature of incisions formed using the techniques herein, it is believed that new meaning is brought to minimally invasive ophthalmic surgery and lens incisions that may be self healing.

In one aspect, a method of making an incision in eye tissue includes generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye while focused at the first depth, focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth, and scanning the beam in the pattern on the eye while focused at the second depth.

In another aspect, a method of making an incision in eye tissue includes generating a beam of light, and passing the beam through a multi-focal length optical element so that a first portion of the beam is focused at a first focal point located at a first depth in the eye tissue and a second portion of the beam is focused at a second focal point located at a second depth in the eye tissue different than first depth.

In yet another aspect, a method of making an incision in eye tissue includes generating a beam of light having at least a first pulse of light and a second pulse of light, and focusing the first and second pulses of light consecutively into the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse arrives before the plasma disappears and is absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In yet one more aspect, a method of making an incision in eye tissue includes generating a beam of light, and focusing the light into the eye tissue to create an elongated column of focused light within the eye tissue, wherein the focusing includes subjecting the light to at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element.

In another aspect, a method of removing a lens and debris from an eye includes generating a beam of light, focusing the light into the eye to fragment the lens into pieces, removing the pieces of lens, and then focusing the light into the eye to ablate debris in the eye.

In one more aspect, a method of removing a lens from a lens capsule in an eye includes generating a beam of light, focusing the light into the eye to form incisions in the lens capsule, inserting an ultrasonic probe through the incision and into the lens capsule to break the lens into pieces, removing the lens pieces from the lens capsule, rinsing the lens capsule to remove endothermial cells therefrom, and inserting at least one of a synthetic. foldable intraocular lens or an optically transparent gel into the lens capsule.

In another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a

beam of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the light beam is focused at multiple focal points in the eye tissue at multiple depths within the eye tissue.

In yet another aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light having at least a first pulse of light and a second pulse of light, a delivery system for focusing the beam onto the eye tissue, a controller for controlling the light source and the delivery system such that the first and second pulses of light are consecutively focused onto the eye tissue, wherein the first pulse creates a plasma at a first depth within the eye tissue, and wherein the second pulse is arrives before the plasma disappears and absorbed by the plasma to extend the plasma in the eye tissue along the beam.

In one more aspect, an ophthalmic surgical system for treating eye tissue includes a light source for generating a beam of light, a delivery system for focusing the beam onto the eye tissue, the delivery system including at least one of a non-spherical lens, a highly focused lens with spherical aberrations, a curved mirror, a cylindrical lens, an adaptive optical element, a prism, and a diffractive optical element, and a controller for controlling the light source and the delivery system such that an elongated column of focused light within the eye tissue is created.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a plan diagram of a system that projects or scans an optical beam into a patient's eye.

FIG. **2** is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule.

FIG. **3** is a planar view of the iris and lens with a circular pattern for the anterior capsulotomy (capsulorexis).

FIG. **4** is a diagram of the line pattern applied across the lens for OCT measurement of the axial profile of the anterior chamber.

FIG. **5** is a diagram of the anterior chamber of the eye and the 3-dimensional laser pattern applied across the lens capsule.

FIG. **6** is an axially-elongated plasma column produced in the focal zone by sequential application of a burst of pulses (**1**, **2**, and **3**) with a delay shorter than the plasma life time.

FIGS. **7**A-**7**B are multi-segmented lenses for focusing the laser beam into 3 points along the same axis.

FIGS. **7**C-**7**D are multi-segmented lenses with co-axial and off-axial segments having focal points along the same axis but different focal distances F**1**, F**2**, F**3**.

FIG. **8** is an axial array of fibers (**1**, **2**, **3**) focused with a set of lenses into multiple points (**1**,**2**,**3**) and thus producing plasma at different depths inside the tissue (**1**, **2**, **3**).

FIG. **9**A and FIG. **9**B are diagrams illustrating examples of the patterns that can be applied for nucleus segmentation.

FIG. **10**A-C is a planar view of some of the combined patterns for segmented capsulotomy and phaco-fragmentation.

FIG. **11** is a plan diagram of one system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **12** is a plan diagram of another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **13** is a plan diagram of yet another system embodiment that projects or scans an optical beam into a patient's eye.

FIG. **14** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal.

FIG. **15** is a flow diagram showing the steps utilized in a "track and treat" approach to material removal that employs user input.

FIG. **16** is a perspective view of a transverse focal zone created by an anamorphic optical scheme.

FIGS. **17**A-**17**C are perspective views of an anamorphic telescope configuration for constructing an inverted Keplerian telescope.

FIG. **18** is a side view of prisms used to extend the beam along a single meridian.

FIG. **19** is a top view illustrating the position and motion of a transverse focal volume on the eye lens.

FIG. **20** illustrates fragmentation patterns of an ocular lens produced by one embodiment of the present invention.

FIG. **21** illustrates circular incisions of an ocular lens produced by one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **1**, such as the system shown in FIG. **1**. The system includes a light source **10** (e.g. laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11** (either cw or pulsed). Control electronics **12** may be a computer, microcontroller, etc. Scanning may be achieved by using one or more moveable optical elements (e.g. lenses, gratings, or as shown in FIG. **1** a mirror(s) **16**) which also may be controlled by control electronics **12**, via input and output device **14**. Mirror **16** may be tilted to deviate the optical beam **11** as shown in FIG. **1**, and direct beam **11** towards the patient's eye **1**. An optional ophthalmic lens **18** can be used to focus the optical beam **11** into the patient's eye **1**. The positioning and character of optical beam **11** and/or the scan pattern it forms on the eye may be further controlled by use of an input device **20** such as a joystick, or any other appropriate user input device.

Techniques herein include utilizing a light source **10** such as a surgical laser configured to provide one or more of the following parameters:

1) pulse energy up to 1 μJ repetition rate up to 1 MHz, pulse duration <1 ps

2) pulse energy up to 10 μJ rep. rate up to 100 kHz, pulse duration <1 ps.

3) Pulse energy up to 1000 μJ, rep rate up to 1 kHz, pulse duration <3 ps.

Additionally, the laser may use wavelengths in a variety of ranges including in the near-infrared range: 800-1100 nm. In one aspect, near-infrared wavelengths are selected because tissue absorption and scattering is reduced. Additionally, a laser can be configured to provide low energy ultrashort pulses of near-infrared radiation with pulse durations below 10 ps or below 1 ps, alone or in combination with pulse energy not exceeding 100 p, at high repetition rate including rates above 1 kHz, and above 10 kHz.

Short pulsed laser light focused into eye tissue **2** will produce dielectric breakdown at the focal point, rupturing the tissue **2** in the vicinity of the photo-induced plasma (see FIG. **2**). The diameter d of the focal point is given by $d=\lambda F/D_b$, where F is the focal length of the last focusing element, D_b is the beam diameter on the last lens, and λ is the wavelength. For a focal length F=160 mm, beam diameter on the last lens D_b=10 mm, and wavelength λ=1.04 um, the focal spot diameter will be $d\approx\lambda/(2\cdot NA)\approx\lambda F/D_b$=15 μm, where the numerical aperture of the focusing optics, $NA\approx D_b/(2F)$.

To provide for continuous cutting, the laser spots should not be separated by more than a width of the crater produced by the laser pulse in tissue. Assuming the rupture zone being R=15 μm (at low energies ionization might occur in the center of the laser spot and not expand to the full spot size), and assuming the maximal diameter of the capsulotomy circle being D_c=8 mm, the number of required pulses will be: $N=\pi D_c/R$=1675 to provide a circular cut line **22** around the circumference of the eye lens **3** as illustrated in FIG. **3**. For smaller diameters ranging from 5-7 mm, the required number of pulses would be less. If the rupture zone were larger (e.g. 50 μm), the number of pulses would drop to N=503.

To produce an accurate circular cut, these pulses should be delivered to tissue over a short eye fixation time. Assuming the fixation time t=0.2 s, laser repetition rate should be: r=N/t=8.4 kHz. If the fixation time were longer, e.g. 0.5 s, the required rep. rate could be reduced to 3.4 kHz. With a rupture zone of 50 μm the rep. rate could further drop to 1 kHz.

Threshold radiant exposure of the dielectric breakdown with 4 ns pulses is about Φ=100 J/cm^2. With a focal spot diameter being d=15 μm, the threshold pulse energy will be $E_{th}=\Phi*\pi d^2/4$=176 μJ. For stable and reproducible operation, pulse energy should exceed the threshold by at least a factor of 2, so pulse energy of the target should be E_b=352 μJ. The creation of a cavitation bubble might take up to 10% of the pulse energy, i.e. E_b=35 μJ. This corresponds to a bubble diameter

$$d_b = \sqrt[3]{\frac{6E_b}{\pi P_a}} = 48\ \mu\text{m}.$$

The energy level can be adjusted to avoid damage to the corneal endothelium. As such, the threshold energy of the dielectric breakdown could be minimized by reducing the pulse duration, for example, in the range of approximately 0.1-1 ps. Threshold radiant exposure, Φ, for dielectric breakdown for 100 fs is about Φ=2 J/cm^2; for 1 ps it is Φ=2.5 J/cm^2. Using the above pulse durations, and a focal spot diameter d=15 μm, the threshold pulse energies will be $E_{th}=\Phi*\pi d^2/4$=3.5 and 4.4 μJ for 100 fs and 1 ps pulses, respectively. The pulse energy could instead be selected to be a multiple of the threshold energy, for example, at least a factor of 2. If a factor of 2 is used, the pulse energies on the target would be E_{th}=7 and 9 μJ, respectively. These are only two examples. Other pulse energy duration times, focal spot sizes and threshold energy levels are possible and are within the scope of the present invention.

A high repetition rate and low pulse energy can be utilized for tighter focusing of the laser beam. In one specific example, a focal distance of F=50 mm is used while the beam diameter remains D_b=10 mm, to provide focusing into a spot of about 4 μm in diameter. Aspherical optics can also be utilized. An 8 mm diameter opening can be completed in a time of 0.2 s using a repetition rate of about 32 kHz.

The laser **10** and controller **12** can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof.

As shown in FIG. **4**, OCT imaging of the anterior chamber can be performed along a simple linear scan **24** across the lens using the same laser and/or the same scanner used to produce the patterns for cutting. This scan will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure. The information may be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes for cutting the lens capsule and segmentation of the lens cortex and nucleus, the thickness of the lens capsule among others. The imaging data may be averaged across a 3-line pattern as shown in FIG. **9**.

An example of the results of such a system on an actual human crystalline lens is shown in FIG. **20**. A beam of 10 μJ, 1 ps pulses delivered at a pulse repetition rate of 50 kHz from a laser operating at a wavelength of 1045 nm was focused at NA=0.05 and scanned from the bottom up in a pattern of 4 circles in 8 axial steps. This produced the fragmentation pattern in the ocular lens shown in FIG. **20**. FIG. **21** shows in detail the resultant circular incisions, which measured ~10 μm in diameter, and ~100 μm in length.

FIG. **2** illustrates an exemplary illustration of the delineation available using the techniques described herein to anatomically define the lens. As can be seen in FIG. **2**, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule. In the most general sense, one aspect of the present invention is the use of ocular imaging data obtained as described herein as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy in novel laser assisted ophthalmic procedures. In fact, the imaging and treatment can be performed using the same

laser and the same scanner. While described for use with lasers, other energy modalities may also be utilized.

It is to be appreciated that plasma formation occurs at the waist of the beam. The axial extent of the cutting zone is determined by the half-length L of the laser beam waist, which can be expressed as: $L \sim \lambda/(4 \cdot NA^2) = dF/D_b$. Thus the lower the NA of the focusing optics, the longer waist of the focused beam, and thus a longer fragmentation zone can be produced. For F=160 mm, beam diameter on the last lens D_b=10 mm, and focal spot diameter d=15 μm, the laser beam waist half-length L would be 240 μm.

With reference to FIG. **5**, a three dimensional application of laser energy **26** can be applied across the capsule along the pattern produced by the laser-induced dielectric breakdown in a number of ways such as, for example:

1) Producing several circular or other pattern scans consecutively at different depths with a step equal to the axial length of the rupture zone. Thus, the depth of the focal point (waist) in the tissue is stepped up or down with each consecutive scan. The laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, axial scanning of the focusing elements or adjusting the optical power of the focusing element while, optionally, simultaneously or sequentially scanning the lateral pattern. The adverse result of laser beam scattering on bubbles, cracks and/or tissue fragments prior to reaching the focal point can be avoided by first producing the pattern/focusing on the maximal required depth in tissue and then, in later passes, focusing on more shallow tissue spaces. Not only does this "bottom up" treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

2) Producing axially-elongated rupture zones at fixed points by:

a) Using a sequence of 2-3 pulses in each spot separated by a few ps. Each pulse will be absorbed by the plasma **28** produced by the previous pulse and thus will extend the plasma **28** upwards along the beam as illustrated in FIG. **6**A. In this approach, the laser energy should be 2 or 3 times higher, i.e. 20-30 μJ. Delay between the consecutive pulses should be longer than the plasma formation time (on the order of 0.1 ps) but not exceed the plasma recombination time (on the order of nanoseconds)

b) Producing an axial sequence of pulses with slightly different focusing points using multiple co-axial beams with different pre-focusing or multifocal optical elements. This can be achieved by using multi-focal optical elements (lenses, mirrors, diffractive optics, etc.). For example, a multi-segmented lens **30** can be used to focus the beam into multiple points (e.g. three separate points) along the same axis, using for example co-axial (see FIGS. **7**A-**7**C) or off-coaxial (see FIG. **7**D) segments to produce varying focal lengths (e.g. F_1, F_2, F_3). The multi-focal element **30** can be co-axial, or off-axis-segmented, or diffractive. Co-axial elements may have more axially-symmetric focal points, but will have different sizes due to the differences in beam diameters in each segment. Off-axial elements might have less symmetric focal points but all the elements can produce the foci of the same sizes.

c) Producing an elongated focusing column (as opposed to just a discrete number of focal points) using: (1) non-spherical (aspherical) optics, or (2) utilizing spherical aberrations in a lens with a high F number, or (3) diffractive optical element (hologram).

d) Producing an elongated zone of ionization using multiple optical fibers. For example, an array of optical fibers **32** of different lengths can be imaged with a set of lenses **34** into multiple focal points at different depths inside the tissue as shown in FIG. **8**.

Patterns of Scanning:

For anterior and posterior capsulotomy, the scanning patterns can be circular and spiral, with a vertical step similar to the length of the rupture zone. For segmentation of the eye lens **3**, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments. Several scan patterns **36** are illustrated in FIGS. **9**A and **9**B, and combinations of scan patterns **38** are illustrated in FIGS. **10**A-**10**C. Beam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial. In addition, these and other 2D and 3D patterns may be used in combination with OCT to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye.

The exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle, and can be used alone to perform capsulotomy. Alternatively, the laser patterning may be used to pre-fragment or segment the nucleus for later conventional ultrasonic phacoemulsification. In this case however, the conventional phacoemulsification would be less than a typical phacoemulsification performed in the absence of the inventive segmenting techniques because the lens has been segmented. As such, the phacoemulsification procedure would likely require less ultrasonic energy to be applied to the eye, allowing for a shortened procedure or requiring less surgical dexterity.

Complications due to the eye movements during surgery can be reduced or eliminated by performing the patterned laser cutting very rapidly (e.g. within a time period that is less than the natural eye fixation time). Depending on the laser power and repetition rate, the patterned cutting can be completed between 5 and 0.5 seconds (or even less), using a laser repetition rate exceeding 1 kHz.

The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole (floaters, membranes, retina), as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris.

Damage to an IOL during posterior capsulotomy can be reduced or minimized by advantageously utilizing a laser pattern initially focused beyond the posterior pole and then gradually moved anteriorly under visual control by the surgeon alone or in combination with imaging data acquired using the techniques described herein.

For proper alignment of the treatment beam pattern, an alignment beam and/or pattern can be first projected onto the target tissue with visible light (indicating where the treatment pattern will be projected. This allows the surgeon to

adjust the size, location and shape of the treatment pattern. Thereafter, the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics **12**) by a short pulsed cutting laser having high repetition rate.

In addition, and in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

The use of an imaging device to guide the treatment beam may be achieved many ways, such as those mentioned above as well as additional examples explained next (which all function to characterize tissue, and continue processing it until a target is removed). For example, in FIG. **11**, a laser source LS and (optional) aiming beam source AIM have outputs that are combined using mirror DM**1** (e.g. dichroic mirror). In this configuration, laser source LS may be used for both therapeutics and diagnostics. This is accomplished by means of mirror M**1** which serves to provide both reference input R and sample input S to an OCT Interferometer by splitting the light beam B (centerlines shown) from laser source LS. Because of the inherent sensitivity of OCT Interferometers, mirror M**1** may be made to reflect only a small portion of the delivered light. Alternatively, a scheme employing polarization sensitive pickoff mirrors may be used in conjunction with a quarter wave plate (not shown) to increase the overall optical efficiency of the system. Lens L**1** may be a single element or a group of elements used to adjust the ultimate size or location along the z-axis of the beam B disposed to the target at point P. When used in conjunction with scanning in the X & Y axes, this configuration enables 3-dimensional scanning and/or variable spot diameters (i.e. by moving the focal point of the light along the z-axis).

In this example, transverse (XY) scanning is achieved by using a pair of orthogonal galvanometric mirrors G**1** & G**2** which may provide 2-dimensional random access scanning of the target. It should be noted that scanning may be achieved in a variety of ways, such as moving mirror M**2**, spinning polygons, translating lenses or curved mirrors, spinning wedges, etc. and that the use of galvanometric scanners does not limit the scope of the overall design. After leaving the scanner, light encounters lens L**2** which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light. Ophthalmic lens OL may be a contact lens and further serve to dampen any motion of eye EYE, allowing for more stable treatment. Lens L**2** may be made to move along the z-axis in coordination with the rest of the optical system to provide for 3-dimensional scanning, both for therapy and diagnosis. In the configuration shown, lens L**2** ideally is moved along with the scanner G**1** & G**2** to maintain telecentricity. With that in mind, one may move the entire optical assembly to adjust the depth along the z-axis. If used with ophthalmic lens OL, the working distance may be precisely held. A device such as the Thorlabs EAS504 precision stepper motor can be used to provide both the length of travel as well as the requisite accuracy and precision to reliably image and treat at clinically meaningful resolutions. As shown it creates a telecentric scan, but need not be limited to such a design.

Mirror M**2** serves to direct the light onto the target, and may be used in a variety of ways. Mirror M**2** could be a dichroic element that the user looks through in order to visualize the target directly or using a camera, or may be made as small as possible to provide an opportunity for the user to view around it, perhaps with a binocular microscope. If a dichroic element is used, it may be made to be photopically neutral to avoid hindering the user's view. An apparatus for visualizing the target tissue is shown schematically as element V, and is preferably a camera with an optional light source for creating an image of the target tissue. The optional aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets. To display the target only, AIM may be pulsed on when the scanner has positioned it over an area deemed to be a target. The output of visualization apparatus V may be brought back to the system via the input/output device **10** and displayed on a screen, such as a graphical user interface GUI. In this example, the entire system is controlled by the controller CPU, and data moved through input/output device **10**. Graphical user interface GUI may be used to process user input, and display the images gathered by both visualization apparatus V and the OCT interferometer. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.

Information about the lateral and axial extent of the cataract and localization of the boundaries of the lens capsule will then be used for determination of the optimal scanning pattern, focusing scheme, and laser parameters for the fragmentation procedure. Much if not all of this information can be obtained from visualization of the target tissue. For example, the axial extent of the fragmentation zone of a single pulse should not exceed the distance between (a) the cataract and the posterior capsule, and (b) the anterior capsule and the corneal endothelium. In the cases of a shallow anterior chamber and/or a large cataract, a shorter fragmentation zone should be selected, and thus more scanning planes will be required. Conversely, for a deep anterior chamber and/or a larger separation between the cataract and the posterior capsule a longer fragmentation zone can be used, and thus less planes of scanning will be required. For this purpose an appropriate focusing element will be selected from an available set. Selection of the optical element will determine the width of the fragmenta-

tion zone, which in turn will determine the spacing between the consecutive pulses. This, in turn, will determine the ratio between the scanning rate and repetition rate of the laser pulses. In addition, the shape of the cataract will determine the boundaries of the fragmentation zone and thus the optimal pattern of the scanner including the axial and lateral extent of the fragmentation zone, the ultimate shape of the scan, number of planes of scanning, etc.

FIG. **12** shows an alternate embodiment in which the imaging and treatment sources are different. A dichroic mirror DM**2** has been added to the configuration of FIG. **11** to combine the imaging and treatment light, and mirror M**1** has been replaced by beam splitter BS which is highly transmissive at the treatment wavelength, but efficiently separates the light from the imaging source SLD for use in the OCT Interferometer. Imaging source SLD may be a superluminescent diode having a spectral output that is nominally 50 nm wide, and centered on or around 835 nm, such as the SuperLum SLD-37. Such a light source is well matched to the clinical application, and sufficiently spectrally distinct from the treatment source, thus allowing for elements DM and BS to be reliably fabricated without the necessarily complicated and expensive optical coatings that would be required if the imaging and treatment sources were closer in wavelength.

FIG. **13** shows an alternate embodiment incorporating a confocal microscope CM for use as an imaging system. In this configuration, mirror M**1** reflects a portion of the backscattered light from beam B into lens L**3**. Lens L**3** serves to focus this light through aperture A (serving as a spatial filter) and ultimately onto detector D. As such, aperture A and point P are optically conjugate, and the signal received by detector D is quite specific when aperture A is made small enough to reject substantially the entire background signal. This signal may thus be used for imaging, as is known in the art. Furthermore, a fluorophore may be introduced into the target to allow for specific marking of either target or healthy tissue. In this approach, the ultrafast laser may be used to pump the absorption band of the fluorophore via a multiphoton process or an alternate source (not shown) could be used in a manner similar to that of FIG. **12**.

FIG. **14** is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.

The system operation of FIG. **14** could be modified to incorporate user input. As shown in FIG. **15**, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).

In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

Laser Delivery System

The laser delivery system in FIG. **1** can be varied in several ways. For example, the laser source could be provided onto a surgical microscope, and the microscope's optics used by the surgeon to apply the laser light, perhaps through the use of a provided console. Alternately, the laser and delivery system would be separate from the surgical microscope and would have an optical system for aligning the aiming beam for cutting. Such a system could swing into position using an articulating arm attached to a console containing the laser at the beginning of the surgery, and then swing away allowing the surgical microscope to swing into position.

The pattern to be applied can be selected from a collection of patterns in the control electronics **12**, produced by the visible aiming beam, then aligned by the surgeon onto the target tissue, and the pattern parameters (including for example, size, number of planar or axial elements, etc.) adjusted as necessary for the size of the surgical field of the particular patient (level of pupil dilation, size of the eye, etc.). Thereafter, the system calculates the number of pulses that should be applied based on the size of the pattern. When the pattern calculations are complete, the laser treatment may be initiated by the user (i.e., press a pedal) for a rapid application of the pattern with a surgical laser.

The laser system can automatically calculate the number of pulses required for producing a certain pattern based on the actual lateral size of the pattern selected by surgeon. This can be performed with the understanding that the rupture zone by the single pulse is fixed (determined by the pulse energy and configuration of the focusing optics), so the number of pulses required for cutting a certain segment is determined as the length of that segment divided by the width of the rupture zone by each pulse. The scanning rate can be linked to the repetition rate of the laser to provide a pulse spacing on tissue determined by the desired distance. The axial step of the scanning pattern will be determined by the length of the rupture zone, which is set by the pulse energy and the configuration of the focusing optics.

Fixation Considerations

The methods and systems described herein can be used alone or in combination with an aplanatic lens (as described in, for example, the U.S. Pat. No. 6,254,595 patent, incorporated herein by reference) or other device to configure the shape of the cornea to assist in the laser methods described herein. A ring, forceps or other securing means may be used to fixate the eye when the procedure exceeds the normal fixation time of the eye. Regardless whether an eye fixation device is used, patterning and segmenting methods described herein may be further subdivided into periods of a duration that may be performed within the natural eye fixation time.

Another potential complication associated with a dense cutting pattern of the lens cortex is the duration of treatment: If a volume of 6×6×4 mm=144 mm^3 of lens is segmented, it will require N=722,000 pulses. If delivered at 50 kHz, it will take 15 seconds, and if delivered at 10 kHz it will take 72 seconds. This is much longer than the natural eye fixation time, and it might require some fixation means for the eye. Thus, only the hardened nucleus may be chosen to be segmented to ease its removal. Determination of its boundaries with the OCT diagnostics will help to minimize the size of the segmented zone and thus the number of pulses, the level of cumulative heating, and the treatment time. If the

segmentation component of the procedure duration exceeds the natural fixation time, then the eye may be stabilized using a conventional eye fixation device.

Thermal Considerations

In cases where very dense patterns of cutting are needed or desired, excess accumulation of heat in the lens may damage the surrounding tissue. To estimate the maximal heating, assume that the bulk of the lens is cut into cubic pieces of 1 mm in size. If tissue is dissected with E_1=10 uJ pulses fragmenting a volume of 15 um in diameter and 200 um in length per pulse, then pulses will be applied each 15 um. Thus a 1×1 mm plane will require 66×66=4356 pulses. The 2 side walls will require 2×66×5=660 pulses, thus total N=5016 pulses will be required per cubic mm of tissue. Since all the laser energy deposited during cutting will eventually be transformed into heat, the temperature elevation will be DT=(E_1*N)/pcV=50.16 mJ/(4.19 mJ/K)=12 K. This will lead to maximal temperature T=37+12° C.=49° C. This heat will dissipate in about one minute due to heat diffusion. Since peripheral areas of the lens will not be segmented (to avoid damage to the lens capsule) the average temperature at the boundaries of the lens will actually be lower. For example, if only half of the lens volume is fragmented, the average temperature elevation at the boundaries of the lens will not exceed 6° C. (T=43° C.) and on the retina will not exceed 0.1 C. Such temperature elevation can be well tolerated by the cells and tissues. However, much higher temperatures might be dangerous and should be avoided.

To reduce heating, a pattern of the same width but larger axial length can be formed, so these pieces can still be removed by suction through a needle. For example, if the lens is cut into pieces of 1×1×4 mm in size, a total of N=6996 pulses will be required per 4 cubic mm of tissue. The temperature elevation will be DT=(E_1*N)/pcV=69.96 mJ/(4.19 mJ/K)/4=1.04 K. Such temperature elevation can be well tolerated by the cells and tissues.

An alternative solution to thermal limitations can be the reduction of the total energy required for segmentation by tighter focusing of the laser beam. In this regime a higher repetition rate and low pulse energy may be used. For example, a focal distance of F=50 mm and a beam diameter of D_b=10 mm would allow for focusing into a spot of about 4 μm in diameter. In this specific example, repetition rate of about 32 kHz provides an 8 mm diameter circle in about 0.2 s.

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm^2. Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm^2. With a retinal zone of about 10 mm in diameter (8 mm pattern size on a lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Transverse Focal Volume

It is also possible to create a transverse focal volume **50** instead of an axial focal volume described above. An anamorphic optical scheme may used to produce a focal zone **39** that is a "line" rather than a single point, as is typical with spherically symmetric elements (see FIG. **16**). As is standard in the field of optical design, the term "anamorphic" is meant herein to describe any system which has different equivalent focal lengths in each meridian. It should be noted that any focal point has a discrete depth of field. However, for tightly focused beams, such as those required to achieve the electric field strength sufficient to disrupt biological material with ultrashort pulses (defined as t_{pulse}<10 ps), the depth of focus is proportionally short.

Such a 1-dimensional focus may be created using cylindrical lenses, and/or mirrors. An adaptive optic may also be used, such as a MEMS mirror or a phased array. When using a phased array, however, careful attention should be paid to the chromatic effects of such a diffractive device. FIGS. **17**A-**17**C illustrate an anamorphic telescope configuration, where cylindrical optics **40***a/b* and spherical lens **42** are used to construct an inverted Keplerian telescope along a single meridian (see FIG. **17**A) thus providing an elongated focal volume transverse to the optical axis (see FIG. **17**C). Compound lenses may be used to allow the beam's final dimensions to be adjustable.

FIG. **18** shows the use of a pair of prisms **46***a/b* to extend the beam along a single meridian, shown as CA. In this example, CA is reduced rather than enlarged to create a linear focal volume.

The focus may also be scanned to ultimately produce patterns. To effect axial changes, the final lens may be made to move along the system's z-axis to translate the focus into the tissue. Likewise, the final lens may be compound, and made to be adjustable. The 1-dimensional focus may also be rotated, thus allowing it to be aligned to produce a variety of patterns, such as those shown in FIGS. **9** and **10**. Rotation may be achieved by rotating the cylindrical element itself. Of course, more than a single element may be used. The focus may also be rotated by using an additional element, such as a Dove prism (not shown). If an adaptive optic is used, rotation may be achieved by rewriting the device, thus streamlining the system design by eliminating a moving part.

The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens, thus planing it. Furthermore, the linear focus may also be used to quickly open the lens capsule, readying it for extraction. It may also be used for any other ocular incision, such as the conjunctiva, etc. (see FIG. **19**).

Cataract Removal Using a Track and Treat Approach

A "track and treat" approach is one that integrates the imaging and treatment aspect of optical eye surgery, for providing an automated approach to removal of debris such as cataractous and cellular material prior to the insertion of an IOL. An ultrafast laser is used to fragment the lens into pieces small enough to be removed using an irrigating/aspirating probe of minimal size without necessarily rupturing the lens capsule. An approach such as this that uses tiny, self-sealing incisions may be used to provide a capsule for filling with a gel or elastomeric IOL. Unlike traditional hard IOLS that require large incisions, a gel or liquid may be used to fill the entire capsule, thus making better use of the body's own accommodative processes. As such, this approach not only addresses cataract, but presbyopia as well.

Alternately, the lens capsule can remain intact, where bilateral incisions are made for aspirating tips, irrigating tips, and ultrasound tips for removing the bulk of the lens. Thereafter, the complete contents of the bag/capsule can be successfully rinsed/washed, which will expel the debris that

can lead to secondary cataracts. Then, with the lens capsule intact, a minimal incision is made for either a foldable IOL or optically transparent gel injected through incision to fill the bag/capsule. The gel would act like the natural lens with a larger accommodating range.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, materials, processes and numerical examples described above are exemplary only, and should not be deemed to limit the claims. Multi-segmented lens **30** can be used to focus the beam simultaneously at multiple points not axially overlapping (i.e. focusing the beam at multiple foci located at different lateral locations on the target tissue). Further, as is apparent from the claims and specification, not all method steps need be performed in the exact order illustrated or claimed, but rather in any order that accomplishes the goals of the surgical procedure.

DETAILED DESCRIPTION OF THE INVENTION

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens;

identify one or more boundaries of crystalline lens based at least in part on the image data;

process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation scanning pattern comprising a planar pattern at a first depth and at one or more additional depths anterior to the first depth;

process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries;

operate the laser and the scanning assembly to scan the focal zone of the laser beam within the lens fragmentation treatment region in the planar pattern at the first depth and to subsequently direct the focal zone of the laser beam at the one or more additional depths anterior to the first depth, thereby effecting patterned laser cutting of lens tissue,

wherein positioning of the focal zone is guided by the control system based on the image data.

2. The system of claim **1**, wherein, the laser beam and scanning assembly are operated to photodisrupt the lens tissue at the first depth so as to form a light scattering region.

3. The system of claim **2**, wherein light scattering region comprises an element selected from the group consisting of a gas bubble, a crack, a tissue fragment, and a tissue rupture.

4. The system of claim **1**, wherein the planar pattern is selected from the group consisting of: two or more intersecting straight lines, a crosshatched pattern comprising two or more sets of intersecting lines, one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines.

5. The system of claim **4**, wherein the planar pattern comprises two or more intersecting straight lines.

6. The system of claim **1**, wherein the lens fragmentation pattern is configured such that the lens is divided into fragments of sufficiently small size so that they may be removed through a lumen of an ophthalmic aspiration probe.

7. The system of claim **6**, wherein the imaging device is selected from the group consisting of a camera, an optical coherence tomography system, a confocal microscope system, and an ultrasound transducer.

8. The system of claim **7**, wherein the imaging device is an optical coherence tomography system.

9. The system of claim **7**, wherein the imaging device is a camera.

10. The system of claim **1**, wherein the lens fragmentation pattern is configured such so as to facilitate prefragmentation of the lens for later phacoemulsification.

11. The system of claim **1**, wherein the lens fragmentation pattern is configured so as divide the lens into fragments of sufficiently small size so that they may be removed through a lumen of an ophthalmic aspiration probe.

12. A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image of a continuous depth profile of the volume of the patient's crystalline lens;

identify one or more boundaries of crystalline lens based at least in part on the image data;

process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries, the lens fragmentation treatment region comprising a posterior cutting boundary located anterior to the posterior capsule of the lens

process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation pattern comprising a scanning pattern at a first depth and at one or more additional depths anterior to the first depth;

operate the laser and the scanning assembly to scan the focal zone of the laser beam within the lens fragmentation treatment region in the scanning pattern at the first depth to photodisrupt at least a portion of lens at the first depth to create a light scattering region and to subsequently direct the focal zone of the laser beam at the one or more additional depths anterior to the first depth, thereby effecting patterned laser cutting of lens tissue,

wherein positioning of the focal zone is guided by the control system based on the image data.

13. The system of claim **12**, wherein light scattering region comprises an element selected from the group consisting of a gas bubble, a crack, a tissue fragment, and a tissue rupture.

14. The system of claim **12**, wherein the planar pattern is selected from the group consisting of: two or more intersecting straight lines, a crosshatched pattern comprising two or more sets of intersecting lines, one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines.

15. The system of claim **14**, wherein the planar pattern comprises two or more intersecting straight lines.

16. The system of claim **12**, wherein the lens fragmentation pattern is configured such that the lens is divided into fragments of sufficiently small size so that they may be removed through a lumen of an ophthalmic aspiration probe.

17. The system of claim **12**, wherein the imaging device is selected from the group consisting of a camera, an optical coherence tomography system, a confocal microscope system, and an ultrasound transducer.

18. The system of claim **17**, wherein the imaging device is an optical coherence tomography system.

19. The system of claim **17**, wherein the imaging device is a camera.

20. The system of claim **12**, wherein the lens fragmentation pattern is configured such so as to facilitate prefragmentation of the lens for later phacoemulsification.

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